

US3772187 (Prod: Paradigm Clinical Research Institute Inc - ClinEdge - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:42:05

All time stamps listed in this document are displayed in GMT

US3772187

Form: Participant Creation

Data signed: (b) (4) 24 Mar 2021 19:08:32

Generated On: 10 Jun 2021 09:42:05

[Participant ID](#)

US3772187

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

US3772187

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Mar 2021 01:06:45

Generated On: 10 Jun 2021 09:42:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 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

US3772187

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Mar 2021 01:06:45

Generated On: 10 Jun 2021 09:42:05

Date of Birth (MMM yyyy)	(b) (6) 1983
Age	37
Age Units	YEARS
Age (Derived)	37
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Mar 2021 01:06:45

Generated On: 10 Jun 2021 09:42:05

Date of Informed Consent (*dd MMM yyyy*) 31 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Mar 2021 01:06:45

Generated On: 10 Jun 2021 09:42:05

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Mar 2021 01:06:45

Generated On: 10 Jun 2021 09:42:05

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Mar 2021 01:06:45

Generated On: 10 Jun 2021 09:42:05

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Mar 2021 01:06:45

Generated On: 10 Jun 2021 09:42:05

Were vital signs assessed? Yes
No

Date of assessment (*dd MMM yyyy*) 31 AUG 2020

Time of assessment (*00:00-23:59*) 10:05 (24 HR)

Vital Signs Date and Time (derived) 31 AUG 2020 10:05

Height (*xxx.x*) 195 cm

Weight (*xxx.x*) 79 kg

BMI (*xxx.x*) 20.77581 kg/m²

BMI units KG/M2

Temperature (*xxx.x*) ND - Not Done

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (*xxx*) ND - Not Done

Pulse units BPM

Respiratory Rate (*xxx*) ND - Not Done

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (*xxx*) ND - Not Done

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (*xxx*) ND - Not Done

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Mar 2021 01:06:45

Generated On: 10 Jun 2021 09:42:05

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

31 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Mar 2021 01:06:45

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes No

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Mar 2021 01:06:45

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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 20:50:20

Generated On: 10 Jun 2021 09:42:05

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 31 AUG 2020

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 20:50:20

Generated On: 10 Jun 2021 09:42:05

What was the date of randomization? (dd MMM yyyy) 31 AUG 2020

What was the participant's randomization number? 110249

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 20:50:20

Generated On: 10 Jun 2021 09:42:05

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 20:50:20

Generated On: 10 Jun 2021 09:42:05

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 (<i>dd MMM yyyy</i>)	31 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:05 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 10:05
Temperature (<i>xxx.x</i>)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	67 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 20:50:20

Generated On: 10 Jun 2021 09:42:05

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)	31 AUG 2020
Time of assessment (00:00-23:59)	11:31 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 11:31
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)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 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 20:50:20

Generated On: 10 Jun 2021 09:42:05

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

31 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 20:50:20

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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) 31 AUG 2020

What was the treatment time? (00:00-23:59) 10:55 (24 HR)

Treatment Date and Time (derived) 31 AUG 2020 10:55

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 20:50:20

Generated On: 10 Jun 2021 09:42:05

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 31 AUG 2020

Collection time (*00:00-23:59*) 10:31 (24 HR)

Collection date and time (derived) 31 AUG 2020 10:31

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 20:50:20

Generated On: 10 Jun 2021 09:42:05

Collection date (<i>dd MMM yyyy</i>)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:33	31 AUG 2020 10:33
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:50:20

Generated On: 10 Jun 2021 09:42:05

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 09:42:05

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 96.6 °F

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

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

PC Time Stamp 31 AUG 2020 11:27

PC Open Date & Time 31 AUG 2020 11:15

PC Close Date & Time 31 AUG 2020 13:45

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

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 97.7 °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 31 AUG 2020 15:47
PC Open Date & Time 31 AUG 2020 14:40
PC Close Date & Time 01 SEP 2020 11:59

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 2

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.1 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 01 SEP 2020 12:02

PC Open Date & Time 01 SEP 2020 12:00

PC Close Date & Time 02 SEP 2020 11:59

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:42:05

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	98.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	02 SEP 2020 20:22
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:42:05

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

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

PC Time Stamp	03 SEP 2020 12:51
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:42:05

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	04 SEP 2020 12:17
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:42:05

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	05 SEP 2020 12:28
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:42:05

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	06 SEP 2020 12:06
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

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

31 AUG 2020 11:29

PC Open Date & Time

31 AUG 2020 11:15

PC Close Date & Time

31 AUG 2020 13:45

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

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.**

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

31 AUG 2020 15:49

PC Open Date & Time

31 AUG 2020 14:40

PC Close Date & Time

01 SEP 2020 11:59

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 2

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	01 SEP 2020 12:03
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 3

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	02 SEP 2020 20:23
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 4

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

03 SEP 2020 12:51

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 5

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

04 SEP 2020 12:17

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 6

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

05 SEP 2020 12:26

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 7

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

06 SEP 2020 12:06

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

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

No

Yes

PC Time stamp	31 AUG 2020 11:30
PC Open Date & Time	31 AUG 2020 11:15
PC Close Date & Time	31 AUG 2020 13:45

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

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

No
Yes

PC Time stamp	31 AUG 2020 15:50
PC Open Date & Time	31 AUG 2020 14:40
PC Close Date & Time	01 SEP 2020 11:59

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:42:05

	Yes <input type="checkbox"/>
PC Time stamp	01 SEP 2020 12:02
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:42:05

	Yes <input type="checkbox"/>
PC Time stamp	02 SEP 2020 20:24
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:42:05

	Yes <input type="checkbox"/>
PC Time stamp	03 SEP 2020 12:51
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:42:05

	Yes <input type="checkbox"/>
PC Time stamp	05 SEP 2020 12:27
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:50:20

Generated On: 10 Jun 2021 09:42:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 09 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3772187

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:50:20

Generated On: 10 Jun 2021 09:42:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3772187

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:50:18

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:50:18

Generated On: 10 Jun 2021 09:42:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3772187

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:50:18

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:50:18

Generated On: 10 Jun 2021 09:42:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3772187

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 20:50:21

Generated On: 10 Jun 2021 09:42:05

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 30 SEP 2020

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID VISIT2

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 20:50:21

Generated On: 10 Jun 2021 09:42:05

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 (<i>dd MMM yyyy</i>)	30 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:43 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 09:43
Temperature (<i>xxx.x</i>)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 20:50:21

Generated On: 10 Jun 2021 09:42:05

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 (<i>dd MMM yyyy</i>)	30 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	11:13 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 11:13
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	70 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3772187

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 20:50:21

Generated On: 10 Jun 2021 09:42:05

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3772187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 20:50:21

Generated On: 10 Jun 2021 09:42:05

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) 30 SEP 2020

What was the treatment time? (00:00-23:59) 10:41 (24 HR)

Treatment Date and Time (derived) 30 SEP 2020 10:41

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

US3772187

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 20:50:21

Generated On: 10 Jun 2021 09:42:05

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 30 SEP 2020

Collection time (*00:00-23:59*) 10:14 (24 HR)

Collection date and time (derived) 30 SEP 2020 10:14

US3772187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 20:50:21

Generated On: 10 Jun 2021 09:42:05

Collection date (<i>dd MMM yyyy</i>)			30 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:18	30 SEP 2020 10:18
Nasopharyngeal Swab 2	No		

US3772187

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:50:21

Generated On: 10 Jun 2021 09:42:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

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 30 SEP 2020 11:13

PC Open Date & Time 30 SEP 2020 11:01

PC Close Date & Time 30 SEP 2020 13:31

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

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 98.4 °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 30 SEP 2020 20:45
PC Open Date & Time 30 SEP 2020 14:26
PC Close Date & Time 01 OCT 2020 11:59

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

PC Time Stamp 01 OCT 2020 15:01

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 3

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 02 OCT 2020 16:05

PC Open Date & Time 02 OCT 2020 12:00

PC Close Date & Time 03 OCT 2020 11:59

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:42:05

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	03 OCT 2020 16:16
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:42:05

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	04 OCT 2020 22:27
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:42:05

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	05 OCT 2020 17:03
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:42:05

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	06 OCT 2020 14:43
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

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

30 SEP 2020 11:14

PC Open Date & Time

30 SEP 2020 11:01

PC Close Date & Time

30 SEP 2020 13:31

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

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

30 SEP 2020 20:45

PC Open Date & Time

30 SEP 2020 14:26

PC Close Date & Time

01 OCT 2020 11:59

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 2

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

01 OCT 2020 15:01

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 3

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	02 OCT 2020 16:05
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 4

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

03 OCT 2020 16:17

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 5

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

04 OCT 2020 22:28

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 6

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	05 OCT 2020 17:03
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 7

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

06 OCT 2020 14:43

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

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

No
Yes

PC Time stamp	30 SEP 2020 11:14
PC Open Date & Time	30 SEP 2020 11:01
PC Close Date & Time	30 SEP 2020 13:31

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

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

No
Yes

PC Time stamp	30 SEP 2020 20:46
PC Open Date & Time	30 SEP 2020 14:26
PC Close Date & Time	01 OCT 2020 11:59

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:42:05

	Yes <input type="checkbox"/>
PC Time stamp	01 OCT 2020 15:02
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:42:05

	Yes <input type="checkbox"/>
PC Time stamp	02 OCT 2020 16:06
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:42:05

	Yes <input type="checkbox"/>
PC Time stamp	03 OCT 2020 16:18
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:42:05

	Yes <input type="checkbox"/>
PC Time stamp	04 OCT 2020 22:28
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:42:05

	Yes <input type="checkbox"/>
PC Time stamp	05 OCT 2020 17:03
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:42:05

	Yes <input type="checkbox"/>
PC Time stamp	06 OCT 2020 14:44
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3772187

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:50:20

Generated On: 10 Jun 2021 09:42:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 7 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3772187

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:50:18

Generated On: 10 Jun 2021 09:42:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3772187

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:50:20

Generated On: 10 Jun 2021 09:42:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 14 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3772187

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:50:20

Generated On: 10 Jun 2021 09:42:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3772187

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:50:20

Generated On: 10 Jun 2021 09:42:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 21 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3772187

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:50:20

Generated On: 10 Jun 2021 09:42:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3772187

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 20:50:21

Generated On: 10 Jun 2021 09:42:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3772187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 20:50:21

Generated On: 10 Jun 2021 09:42:05

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) 02 NOV 2020

Time of assessment (00:00-23:59) 10:30 (24 HR)

Vital Signs Date and Time (derived) 02 NOV 2020 10:30

Temperature (xxx.x) 36.4 C

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) 65 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) 64 mmHg

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

US3772187

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 20:50:21

Generated On: 10 Jun 2021 09:42:05

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.

US3772187

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 20:50:21

Generated On: 10 Jun 2021 09:42:05

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 02 NOV 2020

Collection time (*00:00-23:59*) 10:32 (24 HR)

Collection date and time (derived) 02 NOV 2020 10:32

US3772187

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:50:21

Generated On: 10 Jun 2021 09:42:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3772187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 NOV 2020 16:41:22
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3772187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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 <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	07 NOV 2020 00:03:19
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3772187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 NOV 2020 00:09:04
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 82

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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission	
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 NOV 2020 10:43:58
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	True
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	True
Vomiting	True
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 checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	02 DEC 2020 00:38:00
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 14:33:35
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 DEC 2020 02:14:44
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 DEC 2020 14:01:52
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 DEC 2020 11:54:20
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 JAN 2021 15:37:09
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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 <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 JAN 2021 01:51:31
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	20 JAN 2021 20:26:43
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 JAN 2021 16:10:32
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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	03 FEB 2021 00:13:47
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 08:39:54
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 FEB 2021 00:09:01
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 FEB 2021 09:40:50
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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	03 MAR 2021 11:22:37
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 MAR 2021 14:17:37
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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	17 MAR 2021 10:47:32
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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 <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	24 MAR 2021 07:13:46
Patient Cloud Open Date & Time	24 MAR 2021 00:01
Patient Cloud Close Date & Time	28 MAR 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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 31 MAR 2021 09:48:01

Patient Cloud Open Date & Time 31 MAR 2021 00:01

Patient Cloud Close Date & Time 04 APR 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	07 APR 2021 00:18:15
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	15 APR 2021 07:07:58
Patient Cloud Open Date & Time	14 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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 21 APR 2021 00:05:09

Patient Cloud Open Date & Time 21 APR 2021 00:01

Patient Cloud Close Date & Time 25 APR 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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 29 APR 2021 09:03:38

Patient Cloud Open Date & Time 28 APR 2021 00:01

Patient Cloud Close Date & Time 02 MAY 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 250

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 257

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 264

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission	
Patient Cloud Open Date & Time	19 MAY 2021 00:01
Patient Cloud Close Date & Time	23 MAY 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 271

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 285

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#) 13 JUN 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 292

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission	
Patient Cloud Open Date & Time	16 JUN 2021 00:01
Patient Cloud Close Date & Time	20 JUN 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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 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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 320

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission	
Patient Cloud Open Date & Time	14 JUL 2021 00:01
Patient Cloud Close Date & Time	18 JUL 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2021 00:01
Patient Cloud Close Date & Time	25 JUL 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission	
Patient Cloud Open Date & Time	28 JUL 2021 00:01
Patient Cloud Close Date & Time	01 AUG 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 341

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#) 15 AUG 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission	
Patient Cloud Open Date & Time	15 SEP 2021 00:01
Patient Cloud Close Date & Time	19 SEP 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 404

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#) 10 OCT 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 411

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2021 00:01
Patient Cloud Close Date & Time	17 OCT 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 20 OCT 2021 00:01

[Patient Cloud Close Date & Time](#) 24 OCT 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission	
Patient Cloud Open Date & Time	27 OCT 2021 00:01
Patient Cloud Close Date & Time	31 OCT 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission	
Patient Cloud Open Date & Time	03 NOV 2021 00:01
Patient Cloud Close Date & Time	07 NOV 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 439

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission	
Patient Cloud Open Date & Time	10 NOV 2021 00:01
Patient Cloud Close Date & Time	14 NOV 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission	
Patient Cloud Open Date & Time	17 NOV 2021 00:01
Patient Cloud Close Date & Time	21 NOV 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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 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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 467

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 15 DEC 2021 00:01

[Patient Cloud Close Date & Time](#) 19 DEC 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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 DEC 2021 00:01
Patient Cloud Close Date & Time	02 JAN 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 495

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission	
Patient Cloud Open Date & Time	12 JAN 2022 00:01
Patient Cloud Close Date & Time	16 JAN 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission	
Patient Cloud Open Date & Time	19 JAN 2022 00:01
Patient Cloud Close Date & Time	23 JAN 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 516

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

Patient Cloud Open Date & Time	02 FEB 2022 00:01
Patient Cloud Close Date & Time	06 FEB 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

[Patient Cloud Close Date & Time](#) 13 FEB 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

Patient Cloud Open Date & Time	23 FEB 2022 00:01
Patient Cloud Close Date & Time	27 FEB 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission	
Patient Cloud Open Date & Time	23 MAR 2022 00:01
Patient Cloud Close Date & Time	27 MAR 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission	
Patient Cloud Open Date & Time	30 MAR 2022 00:01
Patient Cloud Close Date & Time	03 APR 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 586

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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 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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission	
Patient Cloud Open Date & Time	20 APR 2022 00:01
Patient Cloud Close Date & Time	24 APR 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 607

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission	
Patient Cloud Open Date & Time	27 APR 2022 00:01
Patient Cloud Close Date & Time	01 MAY 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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
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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 621

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

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

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

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

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

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

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

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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 635

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission	
Patient Cloud Open Date & Time	15 JUN 2022 00:01
Patient Cloud Close Date & Time	19 JUN 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission	
Patient Cloud Open Date & Time	22 JUN 2022 00:01
Patient Cloud Close Date & Time	26 JUN 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 670

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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
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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

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31 JUL 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 712

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

Patient Cloud Open Date & Time	10 AUG 2022 00:01
Patient Cloud Close Date & Time	14 AUG 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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
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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 740

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

Patient Cloud Open Date & Time	07 SEP 2022 00:01
Patient Cloud Close Date & Time	11 SEP 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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 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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission	
Patient Cloud Open Date & Time	14 SEP 2022 00:01
Patient Cloud Close Date & Time	18 SEP 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#) 25 SEP 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 761

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission	
Patient Cloud Open Date & Time	28 SEP 2022 00:01
Patient Cloud Close Date & Time	02 OCT 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission	
Patient Cloud Open Date & Time	05 OCT 2022 00:01
Patient Cloud Close Date & Time	09 OCT 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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°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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 26 OCT 2022 00:01

[Patient Cloud Close Date & Time](#) 30 OCT 2022 23:59

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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
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

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Date and time of submission	
Patient Cloud Open Date & Time	02 NOV 2022 00:01
Patient Cloud Close Date & Time	06 NOV 2022 23:59

US3772187

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:42:05

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		03 MAR 2021 11:22:53

US3772187

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 13 Mar 2021 01:06:45

Generated On: 10 Jun 2021 09:42:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 24 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3772187

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 01:06:45

Generated On: 10 Jun 2021 09:42:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3772187

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 24 Mar 2021 19:00:56

Generated On: 10 Jun 2021 09:42:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 28 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3772187

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 19:08:32

Generated On: 10 Jun 2021 09:42:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3772187

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 24 Mar 2021 19:00:56

Generated On: 10 Jun 2021 09:42:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 27 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3772187

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 19:08:32

Generated On: 10 Jun 2021 09:42:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3772187

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 24 Mar 2021 19:00:56

Generated On: 10 Jun 2021 09:42:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 25 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3772187

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 19:08:32

Generated On: 10 Jun 2021 09:42:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3772187

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 24 Mar 2021 19:08:32

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 02:37:25

Generated On: 10 Jun 2021 09:42:05

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) _____

US3772187

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Mar 2021 19:08:32

Generated On: 10 Jun 2021 09:42:05

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.

US3772187

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Mar 2021 19:08:32

Generated On: 10 Jun 2021 09:42:05

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 22 MAR 2021

Collection time (*00:00-23:59*) 10:32 (24 HR)

Collection date and time (derived) 22 MAR 2021 10:32

US3772187

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 19:08:32

Generated On: 10 Jun 2021 09:42:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3772187

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 03 May 2021 19:24:58

Generated On: 10 Jun 2021 09:42:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 26 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3772187

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 03 May 2021 19:24:58

Generated On: 10 Jun 2021 09:42:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3772187

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

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 _____

US3772187

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

Date of Contact	01 DEC 2020
Time of Contact	12:21
Date and Time of Contact (derived)	01 DEC 2020 12:21
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"/>

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

	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	30 NOV 2020
------	-------------

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

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

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"/>

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

	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 01 DEC 2020

Assessment Not Done False

O2 Saturation ND - Not Done

O2 Saturation Units %

Temperature ND - Not Done

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"/>

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

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"/>

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

	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	02 DEC 2020
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	37.5 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

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"/>

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

	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	03 DEC 2020
------	-------------

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

O2 Saturation	100 %
---------------	-------

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

Temperature	98.9 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

	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	04 DEC 2020
------	-------------

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

O2 Saturation	100 %
---------------	-------

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

Temperature	97.8 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

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"/>

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

	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	05 DEC 2020
------	-------------

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

O2 Saturation	100 %
---------------	-------

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

Temperature	98.5 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

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 01 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

	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	06 DEC 2020
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	100.6 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

Symptom Day

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

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

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

Date	7 DEC 2020
------	------------

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

O2 Saturation	100 %
---------------	-------

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

Temperature	100.6 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 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 01 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

	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 type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input type="radio"/>
	Mild <input checked="" 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 01 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

Symptom Day

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

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

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

Date	8 DEC 2020
------	------------

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

O2 Saturation	99 %
---------------	------

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

Temperature	97.8 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 01 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

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 01 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

	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 DEC 2020
------	-------------

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

O2 Saturation	96 %
---------------	------

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

Temperature	98.0 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

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 01 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

	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 DEC 2020
------	-------------

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

O2 Saturation	100 %
---------------	-------

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

Temperature	98.2 F
-------------	--------

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

Cough	None	<input 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 01 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

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 01 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

	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 DEC 2020
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	98.4 F
-------------	--------

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

Cough	None	<input 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 01 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

Nasal Congestion

- None
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

Date of Visit 02 DEC 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 02 DEC 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 _____

CLIA Certified? Yes
No

COVID-19 Positive (CSA Programming Field Only) 0

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

[Generate Next COVID-19 Assessment](#)

Yes

No

US3772187

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 24 Mar 2021 19:08:32

Generated On: 10 Jun 2021 09:42:05

Visit	Was Saliva Collected?	Date of Collection
Day 3	NA (COVID-19 Negative)	
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3772187

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 24 Mar 2021 19:08:32

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Mar 2021 19:08:32

Generated On: 10 Jun 2021 09:42:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	2 DEC 2020
Time of assessment (<i>00:00-23:59</i>)	11:20 (24 HR)
Vital Signs Date and Time (derived)	2 DEC 2020 11:20
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	37.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	85 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3772187

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Mar 2021 19:08:32

Generated On: 10 Jun 2021 09:42:05

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

2 DEC 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: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 24 Mar 2021 19:08:32

Generated On: 10 Jun 2021 09:42:05

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

Yes

No

NA (COVID-19 Negative)

Date of Collection

2 DEC 2020

US3772187

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

Form: Visit Date

Data signed: (b) (4) 24 Mar 2021 18:53:17

Generated On: 10 Jun 2021 09:42:05

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 28 JAN 2021

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID UNBLND_DECIDE

US3772187

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

Form: Unblinding

Data signed: (b) (4) 24 Mar 2021 18:53:17

Generated On: 10 Jun 2021 09:42:05

Date of updated informed consent (<i>dd MMM yyyy</i>)	28 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	28 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3772187

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 24 Mar 2021 18:53:17

Generated On: 10 Jun 2021 09:42:05

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3772187

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Mar 2021 18:53:17

Generated On: 10 Jun 2021 09:42:05

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 JAN 2021
Time of assessment (00:00-23:59)	12:40 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 12:40
Temperature (xxx.x)	36.6 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3772187

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Mar 2021 18:53:17

Generated On: 10 Jun 2021 09:42:05

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 JAN 2021
Time of assessment (00:00-23:59)	14:15 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 14:15
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)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3772187

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

Form: Physical Examination

Data signed: (b) (4) 24 Mar 2021 18:53:17

Generated On: 10 Jun 2021 09:42:05

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

28 JAN 2021

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

US3772187

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

Form: Exposure

Data signed: (b) (4) 24 Mar 2021 18:53:17

Generated On: 10 Jun 2021 09:42:05

Was study treatment given? Yes
No

If No, reason not given

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

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

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

What was the treatment date? (dd MMM yyyy) 28 JAN 2021

What was the treatment time? (00:00-23:59) 13:43 (24 HR)

Treatment Date and Time (derived) 28 JAN 2021 13:43

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

US3772187

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Mar 2021 18:53:17

Generated On: 10 Jun 2021 09:42:05

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 28 JAN 2021

Collection time (*00:00-23:59*) 12:15 (24 HR)

Collection date and time (derived) 28 JAN 2021 12:15

US3772187

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 24 Mar 2021 18:53:17

Generated On: 10 Jun 2021 09:42:05

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 28 JAN 2021

Collection time (*00:00 - 23:59*) 12:18

Collection Date and Time (derived) 28 JAN 2021 12:18

US3772187

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

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 18:53:17

Generated On: 10 Jun 2021 09:42:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3772187

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 24 Mar 2021 19:00:56

Generated On: 10 Jun 2021 09:42:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 05 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3772187

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 19:08:32

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Mar 2021 19:08:32

Generated On: 10 Jun 2021 09:42:05

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 01 MAR 2021

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID OLD29

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Mar 2021 19:08:32

Generated On: 10 Jun 2021 09:42:05

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 (<i>dd MMM yyyy</i>)	01 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	08:40 (24 HR)
Vital Signs Date and Time (derived)	01 MAR 2021 08:40
Temperature (<i>xxx.x</i>)	36.2 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	75 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Mar 2021 19:08:32

Generated On: 10 Jun 2021 09:42:05

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 (<i>dd MMM yyyy</i>)	01 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	10:30 (24 HR)
Vital Signs Date and Time (derived)	01 MAR 2021 10:30
Temperature (<i>xxx.x</i>)	36.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	72 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3772187

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Mar 2021 19:08:32

Generated On: 10 Jun 2021 09:42:05

Was the physical examination performed?

Yes

No

Date of examination (*dd MMM yyyy*)

01 MAR 2021

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

US3772187

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 24 Mar 2021 19:08:32

Generated On: 10 Jun 2021 09:42:05

Was study treatment given? Yes
No

If No, reason not given

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

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

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

What was the treatment date? (dd MMM yyyy) 01 MAR 2021

What was the treatment time? (00:00-23:59) 09:49 (24 HR)

Treatment Date and Time (derived) 01 MAR 2021 09:49

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

US3772187

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 19:08:32

Generated On: 10 Jun 2021 09:42:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3772187

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Mar 2021 19:00:56

Generated On: 10 Jun 2021 09:42:05

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 8 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3772187

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 19:08:32

Generated On: 10 Jun 2021 09:42:05

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3772187

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 02:37:25

Generated On: 10 Jun 2021 09:42:05

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 31 MAR 2021

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID OLD57

US3772187

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 02:37:25

Generated On: 10 Jun 2021 09:42:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	31 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	09:48 (24 HR)
Vital Signs Date and Time (derived)	31 MAR 2021 09:48
Temperature (<i>xxx.x</i>)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	75 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3772187

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 02:37:25

Generated On: 10 Jun 2021 09:42:05

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.

US3772187

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 02:37:25

Generated On: 10 Jun 2021 09:42:05

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 31 MAR 2021

Collection time (*00:00-23:59*) 09:51 (24 HR)

Collection date and time (derived) 31 MAR 2021 09:51

US3772187

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Mar 2021 01:20:53

Generated On: 10 Jun 2021 09:42:05

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3772187

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 01:20:53

Generated On: 10 Jun 2021 09:42:05

AEID USA-US107-2020-MRNA-1273-P30
1000008

Adverse event APPENDICITIS

Was this a medically-attended AE? Yes
No

Was this a Solicited Adverse Reaction? Yes
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes
No

Start date (dd MMM yyyy) 7 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 7 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 7 DEC 2020

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes
No
Unknown

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 01:20:53

Generated On: 10 Jun 2021 09:42:05

Number of Days in ICU	1
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	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative

US3772187

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 01:20:53

Generated On: 10 Jun 2021 09:42:05

DURING SUBJECT TELEMED
CALL FOR TODAY , SUBJECT
REPORTED THAT THEY ARE AT
THE HOSPITAL AT THE
MOMENT WHERE THEY GOT
DIAGNOSED WITH
APPENDICITIS . ON 08 DEC2020
SITE CALLED THE SUBJECT IN
WHICH THE SUBJECT
REPORTED HAVING
UNDERGONE APPENDECTOMY
ON 07 DEC2020. SITE
REQUESTED MEDICAL
RECORDS FOR THE SUBJECT.
MEDICAL RECORDS RECEIVED
AND SUBJECT WAS
RECHARGED FOR THE
HOSPITAL ON 12-DEC-2020.
MEDICAL RECORDS
CONFIRMED APPENDECTOMY
HAS BEEN DONE.

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)	1

US3772187

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Mar 2021 01:20:53

Generated On: 10 Jun 2021 09:42:05

AEID

Adverse event

APPENDICEAL ABSCESS

Was this a medically-attended AE?

Yes

No

Was this a Solicited Adverse Reaction?

Yes

No

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

Yes

No

Start date (dd MMM yyyy)

07 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

07 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Mar 2021 01:20:53

Generated On: 10 Jun 2021 09:42:05

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product
Withdrawn
Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication False

Concomitant Procedure True

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative DURING THE REVIEW OF MEDICAL RECORDS IT WAS NOTED THE SUBJECT HAD AN APPENDICEAL ABSCESS CAUSED BY THEIR APPENDICITIS. ABSCESS WAS DRAINED DURING THE APPENDECTOMY PROCEDURE.

US3772187

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Mar 2021 01:20:53

Generated On: 10 Jun 2021 09:42:05

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: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 24 Mar 2021 18:53:14

Generated On: 10 Jun 2021 09:42:05

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

Yes

No

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

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 24 Mar 2021 18:53:13

Generated On: 10 Jun 2021 09:42:05

Name of Medication IBUPROFEN

Prophylaxis Yes
No

Indication PAIN AT THE INJECTION SITE

Dose per administration 800

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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US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 24 Mar 2021 18:53:13

Generated On: 10 Jun 2021 09:42:05

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 01 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 01 SEP 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 24 Mar 2021 18:53:13

Generated On: 10 Jun 2021 09:42:05

Name of Medication IBUPROFEN

Prophylaxis Yes
No

Indication HEADACHE

Dose per administration 400

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 24 Mar 2021 18:53:13

Generated On: 10 Jun 2021 09:42:05

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*) 2 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 2 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 24 Mar 2021 18:53:13

Generated On: 10 Jun 2021 09:42:05

Name of Medication TYLENOL

Prophylaxis Yes
No

Indication MYALGIA ABDOMINAL
OBLIQUES

Dose per administration 1000

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 24 Mar 2021 18:53:13

Generated On: 10 Jun 2021 09:42:05

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 01 DEC 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 02 DEC 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 24 Mar 2021 18:53:13

Generated On: 10 Jun 2021 09:42:05

Name of Medication NORCO

Prophylaxis Yes
No

Indication POST APPENDECTOMY

Dose per administration 10/325

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 24 Mar 2021 18:53:13

Generated On: 10 Jun 2021 09:42:05

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*) 8 DEC 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 20 DEC 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 24 Mar 2021 18:53:13

Generated On: 10 Jun 2021 09:42:05

Name of Medication ZOSYN

Prophylaxis Yes
No

Indication POST APPENDECTOMY
INFECTION PROPHYLAXIS

Dose per administration 4.5/100

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 24 Mar 2021 18:53:13

Generated On: 10 Jun 2021 09:42:05

	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)	8 DEC 2020
--------------------------	------------

Start date completely unknown	False
-------------------------------	-------

Ongoing?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

If not Ongoing, End date (dd MMM yyyy)	11 DEC 2020
--	-------------

Was this medication taken for solicited event?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

Separate Dosage Number (derived)	4
----------------------------------	---

Interval Dosage Unit Number (derived)	1
---------------------------------------	---

Interval Dosage Definition (derived)	802 <input type="checkbox"/>
	803 <input type="checkbox"/>
	804 <input checked="" type="checkbox"/>

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 24 Mar 2021 18:53:13

Generated On: 10 Jun 2021 09:42:05

Name of Medication CIPROFLOXACIN

Prophylaxis Yes
No

Indication POST APPENDECTOMY
INFECTION PROPHYLAXIS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 24 Mar 2021 18:53:13

Generated On: 10 Jun 2021 09:42:05

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy)	10 DEC 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

If not Ongoing, End date (dd MMM yyyy)	20 DEC 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"/>

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 24 Mar 2021 18:53:13

Generated On: 10 Jun 2021 09:42:05

Name of Medication METRONIDAZOLE

Prophylaxis Yes
No

Indication POST APPENDECTOMY
INFECTION PROPHYLAXIS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 24 Mar 2021 18:53:13

Generated On: 10 Jun 2021 09:42:05

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy)	10 DEC 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

If not Ongoing, End date (dd MMM yyyy)	20 DEC 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input checked="" type="checkbox"/>

US3772187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 24 Mar 2021 19:08:32

Generated On: 10 Jun 2021 09:42:05

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3772187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 24 Mar 2021 19:08:32

Generated On: 10 Jun 2021 09:42:05

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
7 DEC 2020	APPENDECTOMY	Adverse Event	
07 DEC 2020	ABSCCESS DRAINAGE	Adverse Event	

US3772187

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:42:05

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

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 23 Mar 2021 02:48:56

Generated On: 10 Jun 2021 09:42:05

SAEID	USA-US107-2020-MRNA-1273-P301000008
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)	5

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Mar 2021 02:48:56

Generated On: 10 Jun 2021 09:42:05

SAEID	USA-US107-2020-MRNA-1273-P301000008
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)	5
Date of submission (Pre-filled from custom function)	08/DEC/2020 10:25
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Mar 2021 02:48:56

Generated On: 10 Jun 2021 09:42:05

SAEID	USA-US107-2020-MRNA-1273-P301000008
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)	5
Date of submission (Pre-filled from custom function)	09/DEC/2020 15:26
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.	<input checked="" type="checkbox"/> True

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Mar 2021 02:48:56

Generated On: 10 Jun 2021 09:42:05

SAEID	USA-US107-2020-MRNA-1273-P301000008
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)	5
Date of submission (Pre-filled from custom function)	16/DEC/2020 13:41
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

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Data signed: (b) (4) 23 Mar 2021 02:48:56

Generated On: 10 Jun 2021 09:42:05

SAEID	USA-US107-2020-MRNA-1273-P301000008
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)	5
Date of submission (Pre-filled from custom function)	25/JAN/2021 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.	<input checked="" type="checkbox"/> True

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form (5)

Data signed: (b) (4) 23 Mar 2021 02:48:56

Generated On: 10 Jun 2021 09:42:05

SAEID	USA-US107-2020-MRNA-1273-P301000008
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)	5
Date of submission (Pre-filled from custom function)	08/FEB/2021 12:54
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

US3772187 (Prod: Paradigm Clinical Research Institute Inc - ClinEdge - PPDS)

US3772187

Form: Participant Creation

Generated On: 10 Jun 2021 09:42:05

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:41:45
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'US3772187'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 17:04:32

US3772187

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:06:12
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:54:47

US3772187

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:06:12
User entered '31 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 17:04:33

US3772187

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:06:12
User entered 'Clinic (Clinic)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:54:47

US3772187

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User entered 'SCRN'	System	31 Aug 2020 17:54:47

US3772187

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:07:33
User entered (b) (6) 1983'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 17:04:34

US3772187

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:42:05

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:07:33
User entered '37'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:54:59

US3772187

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:42:05

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User entered 'YEARS'	System	31 Aug 2020 17:54:59

US3772187

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:42:05

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User entered '37'	System	31 Aug 2020 17:55:11

US3772187

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:42:05

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:07:33
User entered 'Male (M)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:54:59

US3772187

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:42:05

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:07:33
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:54:59

US3772187

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:42:05

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:07:33
User entered '1'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:54:59

US3772187

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:42:05

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:07:33
User entered '0'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:54:59

US3772187

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:42:05

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:07:33
User entered '0'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:54:59

US3772187

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:42:05

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:07:33
User entered '0'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:54:59

US3772187

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:42:05

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:07:33
User entered '0'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:54:59

US3772187

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:42:05

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:07:33
User entered '0'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:54:59

US3772187

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:42:05

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:07:33
User entered empty.	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:54:59

US3772187

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:42:05

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:07:33
User entered '0'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:54:59

US3772187

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:42:05

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:07:33
User entered '0'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:54:59

US3772187

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:42:05

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:07:37
User entered '31 Aug 2020'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:55:11

US3772187

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User entered 'Aug 2020'	System	31 Aug 2020 17:55:11

US3772187

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User entered '2020'	System	31 Aug 2020 17:55:11

US3772187

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:42:05

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:07:37
User entered 'Amendment 3 (3)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:55:11

US3772187

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:07:37
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:55:11

US3772187

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:42:05

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:07:37
User entered empty.	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:55:11

US3772187

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:42:05

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:07:37
User entered empty.	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:55:11

US3772187

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:42:05

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:07:37
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:55:11

US3772187

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:42:05

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:07:37
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 17:04:33

US3772187

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:42:05

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User entered '1'	System	31 Aug 2020 17:55:18

US3772187

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:07:44
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:55:18

US3772187

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:42:05

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:07:49
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:55:37

US3772187

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:42:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:07:56
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac disorders, signs and symptoms NEC, HLT: Cardiac signs and symptoms NEC, PT: Palpitations, LLT: Palpitations - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 17:57:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 17:57:37
Data point term sent to Coder	System	31 Aug 2020 17:57:04
User entered 'Palpitations'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:56:41

US3772187

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:07:56
User entered 'un UNK 2000'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:56:41

US3772187

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:42:05

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:07:56
User entered '0'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:56:41

US3772187

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:42:05

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:07:56
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:56:41

US3772187

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:07:56
User entered empty.	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:56:41

US3772187

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:42:05

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:07:56
User entered '0'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:56:41

US3772187

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:42:05

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User entered 'Jan 2000'	System	31 Aug 2020 17:56:41

US3772187

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User entered '2000'	System	31 Aug 2020 17:56:41

US3772187

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User entered empty.	System	31 Aug 2020 17:56:41

US3772187

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User entered empty.	System	31 Aug 2020 17:56:41

US3772187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:01
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:21:37

US3772187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:01
User entered '31 Aug 2020'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:21:37

US3772187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:01
User entered '10:05'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:21:37

US3772187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User entered '31 Aug 2020 10:05'	System	31 Aug 2020 19:21:37

US3772187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:01
User entered '195' cm	Emily Crews (b) (4)	31 Aug 2020 19:21:37
DataPoint set to visible.	(b) (4) System	31 Aug 2020 17:55:18

US3772187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:01
User entered '79' kg	Emily Crews (b) (4)	31 Aug 2020 19:21:37
DataPoint set to visible.	(b) (4) System	31 Aug 2020 17:55:18

US3772187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User entered '20.77581'	System	31 Aug 2020 19:21:37
DataPoint set to visible.	System	31 Aug 2020 17:55:18

US3772187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User entered 'kg/m2'	System	31 Aug 2020 19:21:37
DataPoint set to visible.	System	31 Aug 2020 17:55:18

US3772187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:01
User closed query 'Per CDM: Response noted; however 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)	09 Oct 2020 12:48:14
Query 'Per CDM: Response noted; however 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).	(b) (4), (b) (6)	08 Oct 2020 18:01:50
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 18:01:42
User opened query 'Per CDM: Response noted; however 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)	08 Sep 2020 11:47:10
User entered '36.4' C	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:21:37

US3772187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 18:01:42
User entered 'Oral (Oral)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:21:37

US3772187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:01
User entered empty.	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:21:37

US3772187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 18:01:42
User entered '67'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:21:37

US3772187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User entered 'bpm'	System	31 Aug 2020 19:21:37

US3772187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 18:01:42
User entered '18'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:21:37

US3772187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User entered 'breaths/min'	System	31 Aug 2020 19:21:37

US3772187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 18:01:42
User entered '124'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:21:37

US3772187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User entered 'mmHg'	System	31 Aug 2020 19:21:37

US3772187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 18:01:42
User entered '77'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:21:37

US3772187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User entered 'mmHg'	System	31 Aug 2020 19:21:37

US3772187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12

US3772187

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12

US3772187

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:42:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:07
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:56:55

US3772187

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:42:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:07
User entered '31 Aug 2020'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:56:55

US3772187

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:18
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:26

US3772187

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:18
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:26

US3772187

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:18
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:26

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Folder: Screening

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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)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:18
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:26

US3772187

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:18
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:18
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:26

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:18
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:26

US3772187

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:18
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:18
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:18
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:18
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:42:05

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:18
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:26

US3772187

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:42:05

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:18
User entered empty.	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:26

US3772187

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:42:05

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:26

US3772187

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:18
User entered '0'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:26

US3772187

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:18
User entered '0'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:26

US3772187

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:18
User entered '0'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:18
User entered '0'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:26

US3772187

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:18
User entered '1'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:26

US3772187

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:42:05

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:26

US3772187

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:42:05

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:18
User entered empty.	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:26

US3772187

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 07:37:50
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:23
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:36

US3772187

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 07:37:50
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:23
User entered '31 Aug 2020'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:36

US3772187

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 07:37:50
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:23
User entered 'Clinic (Clinic)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:36

US3772187

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 07:37:50
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User entered 'VISIT1'	System	31 Aug 2020 17:57:36

US3772187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:40:58
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:31
User entered '31 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 17:30:17

US3772187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:42:05

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:40:58
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:31
User entered '110249'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 17:30:17

US3772187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:40:58
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:31
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 17:30:17

US3772187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:42:05

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)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:40:58
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:31
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:47

US3772187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:42:05

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)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:40:58
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:31
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:47

US3772187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:40:58
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:31
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:47

US3772187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:42:05

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:40:58
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:31
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:47

US3772187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:42:05

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:40:58
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:31
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:47

US3772187

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:42:05

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:40:58
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:31
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 22:16:40
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:45:28
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:45:27

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:42:05

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:38
User closed query 'Per CDM: Response noted, however, to avoid duplication of data, kindly consider to manually type as ND (Not done) for Height and Weight on Visit 1 Day 1 page as per CCGs pages 15 & 16 since Screening and VID1 occurred on same day. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 11:50:59
Query 'Per CDM: Response noted, however, to avoid duplication of data, kindly consider to manually type as ND (Not done) for Height and Weight on Visit 1 Day 1 page as per CCGs pages 15 & 16 since Screening and VID1 occurred on same day. Thank you.' answered with 'updated' (Site from DM).	Emily Crews (b) (4) (b) (4)	08 Oct 2020 18:07:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4) (b) (4)	08 Oct 2020 18:07:15
User opened query 'Per CDM: Response noted, however, to avoid duplication of data, kindly consider to manually type as ND (Not done) for Height and Weight on Visit 1 Day 1 page as per CCGs pages 15 & 16 since Screening and VID1 occurred on same day. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 05:10:30
User entered '195' cm	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:23:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:42:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4) (b) (4)	08 Oct 2020 18:07:15
User entered '79' kg	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:42:05

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:38
User closed query 'Per CDM: Response noted, however, to avoid duplication of data, kindly consider to manually type as ND (Not done) for Height and Weight on Visit 1 Day 1 page as per CCGs pages 15 & 16 since Screening and VID1 occurred on same day. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 11:50:59
Query 'Per CDM: Response noted, however, to avoid duplication of data, kindly consider to manually type as ND (Not done) for Height and Weight on Visit 1 Day 1 page as per CCGs pages 15 & 16 since Screening and VID1 occurred on same day. Thank you.' answered with 'updated' (Site from DM).	Emily Crews (b) (4) (b) (4)	08 Oct 2020 18:07:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4) (b) (4)	08 Oct 2020 18:07:15
User opened query 'Per CDM: Response noted, however, to avoid duplication of data, kindly consider to manually type as ND (Not done) for Height and Weight on Visit 1 Day 1 page as per CCGs pages 15 & 16 since Screening and VID1 occurred on same day. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 05:10:30
User entered '195' cm	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:42:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4) (b) (4)	08 Oct 2020 18:07:15
User entered '79' kg	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User accepted default value 'Pre-Dose (PREDOSE)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:38
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:38
User entered '31 Aug 2020'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:38
User entered '10:05'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User entered '31 Aug 2020 10:05'	System	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:38
User entered '36.4' C	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:38
User entered 'Oral (Oral)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:38
User entered empty.	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:38
User entered '67'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User entered 'bpm'	System	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:38
User entered '18'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User entered 'breaths/min'	System	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:38
User entered '124'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User entered 'mmHg'	System	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:38
User entered '77'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User entered 'mmHg'	System	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:42:05

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:38
User closed query 'Per CDM: Response noted, however, to avoid duplication of data, kindly consider to manually type as ND (Not done) for Height and Weight on Visit 1 Day 1 page as per CCGs pages 15 & 16 since Screening and VID1 occurred on same day. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 11:50:59
Query 'Per CDM: Response noted, however, to avoid duplication of data, kindly consider to manually type as ND (Not done) for Height and Weight on Visit 1 Day 1 page as per CCGs pages 15 & 16 since Screening and VID1 occurred on same day. Thank you.' answered with 'updated' (Site from DM).	Emily Crews (b) (4) (b) (4)	08 Oct 2020 18:07:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4) (b) (4)	08 Oct 2020 18:07:15
User opened query 'Per CDM: Response noted, however, to avoid duplication of data, kindly consider to manually type as ND (Not done) for Height and Weight on Visit 1 Day 1 page as per CCGs pages 15 & 16 since Screening and VID1 occurred on same day. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 05:10:30
User entered '195' cm	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:23:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:42:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4) (b) (4)	08 Oct 2020 18:07:15
User entered '79' kg	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User accepted default value 'Post-Dose (POSTDOSE)'	Emily Crews (b) (4)	31 Aug 2020 19:23:08
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:38
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:23:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:38
User entered '31 Aug 2020'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:38
User entered '11:31'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User entered '31 Aug 2020 11:31'	System	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:38
User entered '36.5' C	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:38
User entered 'Oral (Oral)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:38
User entered empty.	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:38
User entered '77'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User entered 'bpm'	System	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:38
User entered '17'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User entered 'breaths/min'	System	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:38
User entered '130'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User entered 'mmHg'	System	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:38
User entered '91'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User entered 'mmHg'	System	31 Aug 2020 19:23:08

US3772187

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:42:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:12
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:42
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:58

US3772187

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:42:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:12
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:42
User entered '31 Aug 2020'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:57:58

US3772187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:16
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:46
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 18:00:07

US3772187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:16
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:46
User entered empty.	Emily Crews (b) (4) (b) (4)	31 Aug 2020 18:00:07

US3772187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:16
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:46
User entered empty.	Emily Crews (b) (4) (b) (4)	31 Aug 2020 18:00:07

US3772187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:16
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User entered 'MRNA-1273 OR PLACEBO'	System	31 Aug 2020 18:00:07

US3772187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:16
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:46
User entered '31 Aug 2020'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 18:00:07

US3772187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:16
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:46
User entered '10:55'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 18:00:07

US3772187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:16
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User entered '31 Aug 2020 10:55'	System	31 Aug 2020 18:00:07

US3772187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:16
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:08:46
User entered 'Left Arm (LEFT ARM)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 18:00:07

US3772187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:16
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 21:08:46
User entered 'ONCE'	System	31 Aug 2020 18:00:07

US3772187

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.		12 Apr 2021 14:41:16
Data hard locked.		03 Apr 2021 09:27:19
User entered 'INTRAMUSCULAR'	System	31 Aug 2020 18:00:07

US3772187

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:42:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:12:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
User closed query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 1 Day 1 with a Collection Date of 31AUG2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 07:32:06
Query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 1 Day 1 with a Collection Date of 31AUG2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' answered with 'Stored on site' (Site from DM).	Emily Crews (b) (4) (b) (4)	05 Nov 2020 23:12:30
User opened query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 1 Day 1 with a Collection Date of 31AUG2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:35:29
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:58:14

US3772187

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:42:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:12:47
User closed query '04Nov2020(b) (6):Please confirm if shipped and provide tracking #. Thank you.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:31:29
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 31AUG2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 07:32:07
Query '04Nov2020(b) (6):Please confirm if shipped and provide tracking #. Thank you.' answered with 'Stored on site' (Site from CRA).	Emily Crews (b) (4)	05 Nov 2020 23:12:33
User opened query '04Nov2020(b) (6):Please confirm if shipped and provide tracking #. Thank you.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 06:19:15
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 31AUG2020; however, it has not been received by GCL. Please clarify.' answered with 'Not yet shipped' (Site from DM).	Sarah Sandberg (b) (4)	08 Oct 2020 17:42:45
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 31AUG2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 09:27:37
User entered '31 Aug 2020'	Emily Crews (b) (4)	31 Aug 2020 17:58:14

US3772187

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:42:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:09:00
User entered '10:31'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:58:14

US3772187

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:42:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User entered '31 Aug 2020 10:31'	System	31 Aug 2020 17:58:14

US3772187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:42:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:09:09
User entered '31 Aug 2020'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:58:30

US3772187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:42:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:58:30

US3772187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:42:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:09:09
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:58:30

US3772187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:42:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:09:09
User entered '10:33'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:58:30

US3772187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:42:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User entered '31 Aug 2020 10:33'	System	31 Aug 2020 17:58:30

US3772187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:42:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:58:30

US3772187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:42:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:09:09
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:58:30

US3772187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:42:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:09:09
User entered empty.	Emily Crews (b) (4) (b) (4)	31 Aug 2020 17:58:30

US3772187

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:42:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User entered empty.	System	31 Aug 2020 17:58:30

US3772187

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:30
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:09:14
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	31 Aug 2020 18:00:18

US3772187

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:41:30
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User entered '1'	System	31 Aug 2020 18:00:18

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T11:26:27', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '3bb4f1d5-de9c-4f8a-82dd-1dbf0c0b6416'	System	31 Aug 2020 18:27:07
User entered 'Yes (Y)'	System	31 Aug 2020 18:27:07

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T11:26:36', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '3bb4f1d5-de9c-4f8a-82dd-1dbf0c0b6416'	System	31 Aug 2020 18:27:07
User entered '96.6'	System	31 Aug 2020 18:27:07

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T11:26:59', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '3bb4f1d5-de9c-4f8a-82dd-1dbf0c0b6416'	System	31 Aug 2020 18:27:07
User entered 'No (N)'	System	31 Aug 2020 18:27:07

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T11:27:04', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '3bb4f1d5-de9c-4f8a-82dd-1dbf0c0b6416'	System	31 Aug 2020 18:27:07
User entered '31 Aug 2020 11:27'	System	31 Aug 2020 18:27:07

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '31 Aug 2020 11:15'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '31 Aug 2020 13:45'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T15:46:24', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'd3ec6151-f2cd-42ed-8cca-956228e0fcea'	System	31 Aug 2020 22:48:02
User entered 'Yes (Y)'	System	31 Aug 2020 22:48:02

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T15:47:43', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'd3ec6151-f2cd-42ed-8cca-956228e0fcea'	System	31 Aug 2020 22:48:02
User entered '97.7'	System	31 Aug 2020 22:48:02

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T15:47:46', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'd3ec6151-f2cd-42ed-8cca-956228e0fcea'	System	31 Aug 2020 22:48:02
User entered 'No (N)'	System	31 Aug 2020 22:48:02

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T15:47:58', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'd3ec6151-f2cd-42ed-8cca-956228e0fcea'	System	31 Aug 2020 22:48:02
User entered '31 Aug 2020 15:47'	System	31 Aug 2020 22:48:02

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '31 Aug 2020 14:40'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered 'Day 2'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:42:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-01T12:00:35', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '8db4a918-6207-4ddf-b065-f0e067c6eb9e'	System	01 Sep 2020 19:02:18
User entered 'Yes (Y)'	System	01 Sep 2020 19:02:18

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:42:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-01T12:01:28', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '8db4a918-6207-4ddf-b065-f0e067c6eb9e' User entered '98.1'	System	01 Sep 2020 19:02:18
	System	01 Sep 2020 19:02:18

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-01T12:01:44', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '8db4a918-6207-4ddf-b065-f0e067c6eb9e'	System	01 Sep 2020 19:02:18
User entered 'Yes (Y)'	System	01 Sep 2020 19:02:18

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
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 'Con med recorded in source' (Site from System).	(b) (4), (b) (6)	10 Sep 2020 15:29:29
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.'	Sarah Sandberg (b) (4) (b) (4)	09 Sep 2020 22:54:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-01T12:02:09', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '8db4a918-6207-4ddf-b065-f0e067c6eb9e'	System	01 Sep 2020 19:02:18
User entered '1'	System	01 Sep 2020 19:02:18

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:42:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-01T12:02:09', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '8db4a918-6207-4ddf-b065-f0e067c6eb9e'	System	01 Sep 2020 19:02:18
User entered '0'	System	01 Sep 2020 19:02:18

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-01T12:02:15', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '8db4a918-6207-4ddf-b065-f0e067c6eb9e'	System	01 Sep 2020 19:02:18
User entered '01 Sep 2020 12:02'	System	01 Sep 2020 19:02:18

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered 'Day 3'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:42:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-02T20:22:37', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '3501b732-90e9-4021-abef-20b368b7a362'	System	03 Sep 2020 03:22:55
User entered 'Yes (Y)'	System	03 Sep 2020 03:22:55

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:42:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-02T20:22:42', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '3501b732-90e9-4021-abef-20b368b7a362'	System	03 Sep 2020 03:22:55
User entered '98.3'	System	03 Sep 2020 03:22:55

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-02T20:22:46', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '3501b732-90e9-4021-abef-20b368b7a362'	System	03 Sep 2020 03:22:55
User entered 'No (N)'	System	03 Sep 2020 03:22:55

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-02T20:22:49', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '3501b732-90e9-4021-abef-20b368b7a362'	System	03 Sep 2020 03:22:55
User entered '02 Sep 2020 20:22'	System	03 Sep 2020 03:22:55

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered 'Day 4'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:42:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-03T12:50:15', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '29aa7887-b7ab-4a80-a465-ecd1a4211dd5'	System	03 Sep 2020 19:51:17
User entered 'Yes (Y)'	System	03 Sep 2020 19:51:17

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:42:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-03T12:51:05', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '29aa7887-b7ab-4a80-a465-ecd1a4211dd5'	System	03 Sep 2020 19:51:17
User entered '97.9'	System	03 Sep 2020 19:51:17

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-03T12:51:13', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '29aa7887-b7ab-4a80-a465-ecd1a4211dd5'	System	03 Sep 2020 19:51:17
User entered 'No (N)'	System	03 Sep 2020 19:51:17

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-03T12:51:15', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '29aa7887-b7ab-4a80-a465-ecd1a4211dd5'	System	03 Sep 2020 19:51:17
User entered '03 Sep 2020 12:51'	System	03 Sep 2020 19:51:17

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered 'Day 5'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:42:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-04T12:16:49', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '9643d9c1-368e-40fb-ae81-7e157bbed3a9'	System	04 Sep 2020 19:17:14
User entered 'Yes (Y)'	System	04 Sep 2020 19:17:14

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:42:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-04T12:17:03', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '9643d9c1-368e-40fb-ae81-7e157bbbed3a9'	System	04 Sep 2020 19:17:14
User entered '98.0'	System	04 Sep 2020 19:17:14

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-04T12:17:05', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '9643d9c1-368e-40fb-ae81-7e157bbed3a9'	System	04 Sep 2020 19:17:14
User entered 'No (N)'	System	04 Sep 2020 19:17:14

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-04T12:17:09', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '9643d9c1-368e-40fb-ae81-7e157bbed3a9'	System	04 Sep 2020 19:17:14
User entered '04 Sep 2020 12:17'	System	04 Sep 2020 19:17:14

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered 'Day 6'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:42:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-05T12:27:57', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'd9f53859-425b-431d-a59c-202ffcaed1d1'	System	05 Sep 2020 19:28:14
User entered 'Yes (Y)'	System	05 Sep 2020 19:28:14

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:42:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-05T12:28:05', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'd9f53859-425b-431d-a59c-202ffcaed1d1'	System	05 Sep 2020 19:28:14
User entered '98.1'	System	05 Sep 2020 19:28:14

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-05T12:28:07', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'd9f53859-425b-431d-a59c-202ffcaed1d1'	System	05 Sep 2020 19:28:14
User entered 'No (N)'	System	05 Sep 2020 19:28:14

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-05T12:28:11', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'd9f53859-425b-431d-a59c-202ffcaed1d1'	System	05 Sep 2020 19:28:14
User entered '05 Sep 2020 12:28'	System	05 Sep 2020 19:28:14

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered 'Day 7'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:42:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-06T12:06:19', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '61d150e7-51fb-485c-bfe7-f3e9c6df927a'	System	06 Sep 2020 19:06:45
User entered 'Yes (Y)'	System	06 Sep 2020 19:06:45

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:42:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-06T12:06:23', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '61d150e7-51fb-485c-bfe7-f3e9c6df927a'	System	06 Sep 2020 19:06:45
User entered '97.8'	System	06 Sep 2020 19:06:45

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-06T12:06:38', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '61d150e7-51fb-485c-bfe7-f3e9c6df927a'	System	06 Sep 2020 19:06:45
User entered 'No (N)'	System	06 Sep 2020 19:06:45

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-06T12:06:42', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '61d150e7-51fb-485c-bfe7-f3e9c6df927a'	System	06 Sep 2020 19:06:45
User entered '06 Sep 2020 12:06'	System	06 Sep 2020 19:06:45

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T11:28:25', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '033ff6f7-13bb-4781-bd2c-16d8fe34ac46'	System	31 Aug 2020 18:29:21
User entered 'Does not interfere with activity (2)'	System	31 Aug 2020 18:29:21

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T11:28:33', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '033ff6f7-13bb-4781-bd2c-16d8fe34ac46'	System	31 Aug 2020 18:29:21
User entered 'No (N)'	System	31 Aug 2020 18:29:21

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T11:28:41', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '033ff6f7-13bb-4781-bd2c-16d8fe34ac46'	System	31 Aug 2020 18:29:21
User entered 'No (N)'	System	31 Aug 2020 18:29:21

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T11:29:10', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '033ff6f7-13bb-4781-bd2c-16d8fe34ac46'	System	31 Aug 2020 18:29:21
User entered 'Does not interfere with activity (2)'	System	31 Aug 2020 18:29:21

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T11:29:17', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '033ff6f7-13bb-4781-bd2c-16d8fe34ac46'	System	31 Aug 2020 18:29:21
User entered '31 Aug 2020 11:29'	System	31 Aug 2020 18:29:21

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '31 Aug 2020 11:15'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '31 Aug 2020 13:45'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T15:48:18', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '4c6904a3-f08f-4f80-9b6d-a516473f69dd'	System	31 Aug 2020 22:49:39
User entered 'Does not interfere with activity (2)'	System	31 Aug 2020 22:49:39

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T15:48:34', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '4c6904a3-f08f-4f80-9b6d-a516473f69dd'	System	31 Aug 2020 22:49:39
User entered 'Yes (Y)'	System	31 Aug 2020 22:49:39

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T15:49:18', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '4c6904a3-f08f-4f80-9b6d-a516473f69dd'	System	31 Aug 2020 22:49:39
User entered '1'	System	31 Aug 2020 22:49:39

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T15:49:21', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '4c6904a3-f08f-4f80-9b6d-a516473f69dd'	System	31 Aug 2020 22:49:39
User entered 'No (N)'	System	31 Aug 2020 22:49:39

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T15:49:29', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '4c6904a3-f08f-4f80-9b6d-a516473f69dd'	System	31 Aug 2020 22:49:39
User entered 'None (1)'	System	31 Aug 2020 22:49:39

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T15:49:34', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '4c6904a3-f08f-4f80-9b6d-a516473f69dd'	System	31 Aug 2020 22:49:39
User entered '31 Aug 2020 15:49'	System	31 Aug 2020 22:49:39

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '31 Aug 2020 14:40'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered 'Day 2'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-01T12:02:59', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'adc930a9-cd14-4608-9e7a-3bfa17b515e8'	System	01 Sep 2020 19:03:18
User entered 'None (1)'	System	01 Sep 2020 19:03:18

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-01T12:03:02', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'adc930a9-cd14-4608-9e7a-3bfa17b515e8'	System	01 Sep 2020 19:03:18
User entered 'No (N)'	System	01 Sep 2020 19:03:18

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-01T12:03:06', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'adc930a9-cd14-4608-9e7a-3bfa17b515e8'	System	01 Sep 2020 19:03:18
User entered 'No (N)'	System	01 Sep 2020 19:03:18

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-01T12:03:13', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'adc930a9-cd14-4608-9e7a-3bfa17b515e8'	System	01 Sep 2020 19:03:18
User entered 'None (1)'	System	01 Sep 2020 19:03:18

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-01T12:03:15', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'adc930a9-cd14-4608-9e7a-3bfa17b515e8'	System	01 Sep 2020 19:03:18
User entered '01 Sep 2020 12:03'	System	01 Sep 2020 19:03:18

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered 'Day 3'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-02T20:22:53', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '71481912-1b13-4688-a8b8-1bcd98625db0'	System	03 Sep 2020 03:23:10
User entered 'None (1)'	System	03 Sep 2020 03:23:10

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-02T20:22:56', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '71481912-1b13-4688-a8b8-1bcd98625db0'	System	03 Sep 2020 03:23:10
User entered 'No (N)'	System	03 Sep 2020 03:23:10

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-02T20:22:58', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '71481912-1b13-4688-a8b8-1bcd98625db0'	System	03 Sep 2020 03:23:10
User entered 'No (N)'	System	03 Sep 2020 03:23:10

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-02T20:23:01', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '71481912-1b13-4688-a8b8-1bcd98625db0'	System	03 Sep 2020 03:23:10
User entered 'None (1)'	System	03 Sep 2020 03:23:10

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-02T20:23:06', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '71481912-1b13-4688-a8b8-1bcd98625db0'	System	03 Sep 2020 03:23:10
User entered '02 Sep 2020 20:23'	System	03 Sep 2020 03:23:10

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered 'Day 4'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-03T12:51:21', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '490c5623-fbd3-46e6-8cbd-51ff31328438'	System	03 Sep 2020 19:51:37
User entered 'None (1)'	System	03 Sep 2020 19:51:37

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-03T12:51:23', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '490c5623-fbd3-46e6-8cbd-51ff31328438'	System	03 Sep 2020 19:51:37
User entered 'No (N)'	System	03 Sep 2020 19:51:37

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-03T12:51:26', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '490c5623-fbd3-46e6-8cbd-51ff31328438'	System	03 Sep 2020 19:51:37
User entered 'No (N)'	System	03 Sep 2020 19:51:37

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-03T12:51:31', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '490c5623-fbd3-46e6-8cbd-51ff31328438'	System	03 Sep 2020 19:51:37
User entered 'None (1)'	System	03 Sep 2020 19:51:37

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-03T12:51:34', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '490c5623-fbd3-46e6-8cbd-51ff31328438'	System	03 Sep 2020 19:51:37
User entered '03 Sep 2020 12:51'	System	03 Sep 2020 19:51:37

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered 'Day 5'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-04T12:17:13', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'aac3deb0-177d-479b-a437-5c92bfab86c6'	System	04 Sep 2020 19:17:45
User entered 'None (1)'	System	04 Sep 2020 19:17:45

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-04T12:17:19', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'aac3deb0-177d-479b-a437-5c92bfab86c6'	System	04 Sep 2020 19:17:45
User entered 'No (N)'	System	04 Sep 2020 19:17:45

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-04T12:17:22', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'aac3deb0-177d-479b-a437-5c92bfab86c6'	System	04 Sep 2020 19:17:45
User entered 'No (N)'	System	04 Sep 2020 19:17:45

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-04T12:17:38', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'aac3deb0-177d-479b-a437-5c92bfab86c6'	System	04 Sep 2020 19:17:45
User entered 'None (1)'	System	04 Sep 2020 19:17:45

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-04T12:17:40', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'aac3deb0-177d-479b-a437-5c92bfab86c6'	System	04 Sep 2020 19:17:45
User entered '04 Sep 2020 12:17'	System	04 Sep 2020 19:17:45

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered 'Day 6'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-05T12:26:47', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '7c60b176-90cd-43f1-b31d-87f02cd1f9df'	System	05 Sep 2020 19:26:59
User entered 'None (1)'	System	05 Sep 2020 19:26:59

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-05T12:26:49', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '7c60b176-90cd-43f1-b31d-87f02cd1f9df'	System	05 Sep 2020 19:26:59
User entered 'No (N)'	System	05 Sep 2020 19:26:59

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-05T12:26:51', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '7c60b176-90cd-43f1-b31d-87f02cd1f9df'	System	05 Sep 2020 19:26:59
User entered 'No (N)'	System	05 Sep 2020 19:26:59

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-05T12:26:54', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '7c60b176-90cd-43f1-b31d-87f02cd1f9df'	System	05 Sep 2020 19:26:59
User entered 'None (1)'	System	05 Sep 2020 19:26:59

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-05T12:26:57', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '7c60b176-90cd-43f1-b31d-87f02cd1f9df'	System	05 Sep 2020 19:26:59
User entered '05 Sep 2020 12:26'	System	05 Sep 2020 19:26:59

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered 'Day 7'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-06T12:06:46', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '45ac5b90-b4b7-451a-b3e3-2b0e9065f324'	System	06 Sep 2020 19:07:00
User entered 'None (1)'	System	06 Sep 2020 19:07:00

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-06T12:06:48', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '45ac5b90-b4b7-451a-b3e3-2b0e9065f324'	System	06 Sep 2020 19:07:00
User entered 'No (N)'	System	06 Sep 2020 19:07:00

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-06T12:06:52', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '45ac5b90-b4b7-451a-b3e3-2b0e9065f324'	System	06 Sep 2020 19:07:00
User entered 'No (N)'	System	06 Sep 2020 19:07:00

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-06T12:06:54', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '45ac5b90-b4b7-451a-b3e3-2b0e9065f324'	System	06 Sep 2020 19:07:00
User entered 'None (1)'	System	06 Sep 2020 19:07:00

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-06T12:06:57', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '45ac5b90-b4b7-451a-b3e3-2b0e9065f324'	System	06 Sep 2020 19:07:00
User entered '06 Sep 2020 12:06'	System	06 Sep 2020 19:07:00

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T11:29:24', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'acd7487d-4aea-473d-bfc1-f9532b074ef6'	System	31 Aug 2020 18:30:24
User entered 'None (0)'	System	31 Aug 2020 18:30:24

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T11:29:29', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'acd7487d-4aea-473d-bfc1-f9532b074ef6'	System	31 Aug 2020 18:30:24
User entered 'None (0)'	System	31 Aug 2020 18:30:24

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T11:29:32', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'acd7487d-4aea-473d-bfc1-f9532b074ef6'	System	31 Aug 2020 18:30:24
User entered 'None (0)'	System	31 Aug 2020 18:30:24

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T11:29:37', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'acd7487d-4aea-473d-bfc1-f9532b074ef6'	System	31 Aug 2020 18:30:24
User entered 'None (0)'	System	31 Aug 2020 18:30:24

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T11:29:39', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'acd7487d-4aea-473d-bfc1-f9532b074ef6'	System	31 Aug 2020 18:30:24
User entered 'None (0)'	System	31 Aug 2020 18:30:24

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T11:29:42', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'acd7487d-4aea-473d-bfc1-f9532b074ef6'	System	31 Aug 2020 18:30:24
User entered 'None (0)'	System	31 Aug 2020 18:30:24

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T11:29:50', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'acd7487d-4aea-473d-bfc1-f9532b074ef6'	System	31 Aug 2020 18:30:24
User entered 'No (N)'	System	31 Aug 2020 18:30:24

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T11:30:22', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'acd7487d-4aea-473d-bfc1-f9532b074ef6'	System	31 Aug 2020 18:30:24
User entered '31 Aug 2020 11:30'	System	31 Aug 2020 18:30:24

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '31 Aug 2020 11:15'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '31 Aug 2020 13:45'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T15:49:43', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '8524539d-e5dd-4c45-8df8-2a4cb6ef1234'	System	01 Sep 2020 01:06:33
User entered 'None (0)'	System	01 Sep 2020 01:06:33

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T15:49:47', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '8524539d-e5dd-4c45-8df8-2a4cb6ef1234'	System	01 Sep 2020 01:06:33
User entered 'No interference with activity (1)'	System	01 Sep 2020 01:06:33

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T15:49:51', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '8524539d-e5dd-4c45-8df8-2a4cb6ef1234'	System	01 Sep 2020 01:06:33
User entered 'None (0)'	System	01 Sep 2020 01:06:33

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T15:49:55', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '8524539d-e5dd-4c45-8df8-2a4cb6ef1234'	System	01 Sep 2020 01:06:33
User entered 'None (0)'	System	01 Sep 2020 01:06:33

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T15:49:57', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '8524539d-e5dd-4c45-8df8-2a4cb6ef1234'	System	01 Sep 2020 01:06:33
User entered 'None (0)'	System	01 Sep 2020 01:06:33

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T15:50:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '8524539d-e5dd-4c45-8df8-2a4cb6ef1234'	System	01 Sep 2020 01:06:33
User entered 'None (0)'	System	01 Sep 2020 01:06:33

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T15:50:05', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '8524539d-e5dd-4c45-8df8-2a4cb6ef1234'	System	01 Sep 2020 01:06:33
User entered 'No (N)'	System	01 Sep 2020 01:06:33

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-08-31T15:50:07', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '8524539d-e5dd-4c45-8df8-2a4cb6ef1234'	System	01 Sep 2020 01:06:33
User entered '31 Aug 2020 15:50'	System	01 Sep 2020 01:06:33

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '31 Aug 2020 14:40'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered 'Day 2'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:42:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-01T12:02:24', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '1338a882-d03f-4806-b584-b72f8ae9721f'	System	01 Sep 2020 19:02:54
User entered 'No interference with activity (1)'	System	01 Sep 2020 19:02:54

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:42:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-01T12:02:33', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '1338a882-d03f-4806-b584-b72f8ae9721f'	System	01 Sep 2020 19:02:54
User entered 'Some interference with activity (2)'	System	01 Sep 2020 19:02:54

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:42:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-01T12:02:35', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '1338a882-d03f-4806-b584-b72f8ae9721f'	System	01 Sep 2020 19:02:54
User entered 'None (0)'	System	01 Sep 2020 19:02:54

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:42:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-01T12:02:42', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '1338a882-d03f-4806-b584-b72f8ae9721f'	System	01 Sep 2020 19:02:54
User entered 'None (0)'	System	01 Sep 2020 19:02:54

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:42:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-01T12:02:44', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '1338a882-d03f-4806-b584-b72f8ae9721f'	System	01 Sep 2020 19:02:54
User entered 'None (0)'	System	01 Sep 2020 19:02:54

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:42:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-01T12:02:47', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '1338a882-d03f-4806-b584-b72f8ae9721f'	System	01 Sep 2020 19:02:54
User entered 'None (0)'	System	01 Sep 2020 19:02:54

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-01T12:02:49', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '1338a882-d03f-4806-b584-b72f8ae9721f'	System	01 Sep 2020 19:02:54
User entered 'No (N)'	System	01 Sep 2020 19:02:54

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:42:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-01T12:02:51', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '1338a882-d03f-4806-b584-b72f8ae9721f'	System	01 Sep 2020 19:02:54
User entered '01 Sep 2020 12:02'	System	01 Sep 2020 19:02:54

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered 'Day 3'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:42:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-02T20:23:40', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '171ad297-a1ab-40b3-86ae-ba11693e978e'	System	03 Sep 2020 03:24:18
User entered 'No interference with activity (1)'	System	03 Sep 2020 03:24:18

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:42:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-02T20:23:49', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '171ad297-a1ab-40b3-86ae-ba11693e978e'	System	03 Sep 2020 03:24:18
User entered 'Some interference with activity (2)'	System	03 Sep 2020 03:24:18

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:42:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-02T20:23:53', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '171ad297-a1ab-40b3-86ae-ba11693e978e'	System	03 Sep 2020 03:24:18
User entered 'None (0)'	System	03 Sep 2020 03:24:18

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:42:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-02T20:24:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '171ad297-a1ab-40b3-86ae-ba11693e978e'	System	03 Sep 2020 03:24:18
User entered 'None (0)'	System	03 Sep 2020 03:24:18

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:42:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-02T20:24:03', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '171ad297-a1ab-40b3-86ae-ba11693e978e'	System	03 Sep 2020 03:24:18
User entered 'None (0)'	System	03 Sep 2020 03:24:18

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:42:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-02T20:24:06', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '171ad297-a1ab-40b3-86ae-ba11693e978e'	System	03 Sep 2020 03:24:18
User entered 'None (0)'	System	03 Sep 2020 03:24:18

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-02T20:24:11', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '171ad297-a1ab-40b3-86ae-ba11693e978e'	System	03 Sep 2020 03:24:18
User entered 'No (N)'	System	03 Sep 2020 03:24:18

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:42:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-02T20:24:13', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '171ad297-a1ab-40b3-86ae-ba11693e978e'	System	03 Sep 2020 03:24:18
User entered '02 Sep 2020 20:24'	System	03 Sep 2020 03:24:18

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered 'Day 4'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:42:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-03T12:51:39', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'fe16eff1-e0b7-4571-a414-85811b859ce6'	System	03 Sep 2020 19:52:01
User entered 'None (0)'	System	03 Sep 2020 19:52:01

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:42:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-03T12:51:42', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'fe16eff1-e0b7-4571-a414-85811b859ce6'	System	03 Sep 2020 19:52:01
User entered 'No interference with activity (1)'	System	03 Sep 2020 19:52:01

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:42:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-03T12:51:44', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'fe16eff1-e0b7-4571-a414-85811b859ce6'	System	03 Sep 2020 19:52:01
User entered 'None (0)'	System	03 Sep 2020 19:52:01

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:42:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-03T12:51:46', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'fe16eff1-e0b7-4571-a414-85811b859ce6'	System	03 Sep 2020 19:52:01
User entered 'None (0)'	System	03 Sep 2020 19:52:01

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:42:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-03T12:51:49', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'fe16eff1-e0b7-4571-a414-85811b859ce6'	System	03 Sep 2020 19:52:01
User entered 'None (0)'	System	03 Sep 2020 19:52:01

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:42:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-03T12:51:52', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'fe16eff1-e0b7-4571-a414-85811b859ce6'	System	03 Sep 2020 19:52:01
User entered 'None (0)'	System	03 Sep 2020 19:52:01

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-03T12:51:55', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'fe16eff1-e0b7-4571-a414-85811b859ce6'	System	03 Sep 2020 19:52:01
User entered 'No (N)'	System	03 Sep 2020 19:52:01

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:42:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-03T12:51:57', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'fe16eff1-e0b7-4571-a414-85811b859ce6'	System	03 Sep 2020 19:52:01
User entered '03 Sep 2020 12:51'	System	03 Sep 2020 19:52:01

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered 'Day 5'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:42:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-04T12:17:44', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '33579df7-d2fe-4f72-8f62-1a1059bb9d34'	System	04 Sep 2020 19:18:04
User entered 'None (0)'	System	04 Sep 2020 19:18:04

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:42:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-04T12:17:47', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '33579df7-d2fe-4f72-8f62-1a1059bb9d34'	System	04 Sep 2020 19:18:04
User entered 'None (0)'	System	04 Sep 2020 19:18:04

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:42:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-04T12:17:49', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '33579df7-d2fe-4f72-8f62-1a1059bb9d34'	System	04 Sep 2020 19:18:04
User entered 'None (0)'	System	04 Sep 2020 19:18:04

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:42:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-04T12:17:51', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '33579df7-d2fe-4f72-8f62-1a1059bb9d34'	System	04 Sep 2020 19:18:04
User entered 'None (0)'	System	04 Sep 2020 19:18:04

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:42:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-04T12:17:53', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '33579df7-d2fe-4f72-8f62-1a1059bb9d34'	System	04 Sep 2020 19:18:04
User entered 'None (0)'	System	04 Sep 2020 19:18:04

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:42:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-04T12:17:55', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '33579df7-d2fe-4f72-8f62-1a1059bb9d34'	System	04 Sep 2020 19:18:04
User entered 'None (0)'	System	04 Sep 2020 19:18:04

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-04T12:17:58', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '33579df7-d2fe-4f72-8f62-1a1059bb9d34'	System	04 Sep 2020 19:18:04
User entered 'No (N)'	System	04 Sep 2020 19:18:04

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:42:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-04T12:18:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '33579df7-d2fe-4f72-8f62-1a1059bb9d34'	System	04 Sep 2020 19:18:04
User entered '04 Sep 2020 12:18'	System	04 Sep 2020 19:18:04

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered 'Day 6'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:42:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-05T12:27:19', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '3d9677e9-cd13-49f0-aa7d-13f456776476'	System	05 Sep 2020 19:27:55
User entered 'None (0)'	System	05 Sep 2020 19:27:55

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:42:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-05T12:27:31', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '3d9677e9-cd13-49f0-aa7d-13f456776476'	System	05 Sep 2020 19:27:55
User entered 'None (0)'	System	05 Sep 2020 19:27:55

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:42:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-05T12:27:35', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '3d9677e9-cd13-49f0-aa7d-13f456776476'	System	05 Sep 2020 19:27:55
User entered 'None (0)'	System	05 Sep 2020 19:27:55

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:42:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-05T12:27:37', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '3d9677e9-cd13-49f0-aa7d-13f456776476'	System	05 Sep 2020 19:27:55
User entered 'None (0)'	System	05 Sep 2020 19:27:55

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:42:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-05T12:27:42', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '3d9677e9-cd13-49f0-aa7d-13f456776476'	System	05 Sep 2020 19:27:55
User entered 'None (0)'	System	05 Sep 2020 19:27:55

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:42:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-05T12:27:46', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '3d9677e9-cd13-49f0-aa7d-13f456776476'	System	05 Sep 2020 19:27:55
User entered 'None (0)'	System	05 Sep 2020 19:27:55

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-05T12:27:48', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '3d9677e9-cd13-49f0-aa7d-13f456776476'	System	05 Sep 2020 19:27:55
User entered 'No (N)'	System	05 Sep 2020 19:27:55

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:42:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-05T12:27:51', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '3d9677e9-cd13-49f0-aa7d-13f456776476'	System	05 Sep 2020 19:27:55
User entered '05 Sep 2020 12:27'	System	05 Sep 2020 19:27:55

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered 'Day 7'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:42:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-06T12:07:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '07ffd07b-6ec5-459f-9397-79fbf147ddf'	System	06 Sep 2020 19:07:17
User entered 'None (0)'	System	06 Sep 2020 19:07:17

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:42:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-06T12:07:02', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '07ffd07b-6ec5-459f-9397-79fbf147ddfe'	System	06 Sep 2020 19:07:17
User entered 'None (0)'	System	06 Sep 2020 19:07:17

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:42:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-06T12:07:04', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '07ffd07b-6ec5-459f-9397-79fbf147ddfe'	System	06 Sep 2020 19:07:17
User entered 'None (0)'	System	06 Sep 2020 19:07:17

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:42:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-06T12:07:07', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '07ffd07b-6ec5-459f-9397-79fbf147ddfe'	System	06 Sep 2020 19:07:17
User entered 'None (0)'	System	06 Sep 2020 19:07:17

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:42:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-06T12:07:08', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '07ffd07b-6ec5-459f-9397-79fbf147ddfe'	System	06 Sep 2020 19:07:17
User entered 'None (0)'	System	06 Sep 2020 19:07:17

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:42:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-06T12:07:09', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '07ffd07b-6ec5-459f-9397-79fbf147ddfe'	System	06 Sep 2020 19:07:17
User entered 'None (0)'	System	06 Sep 2020 19:07:17

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-06T12:07:12', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '07ffd07b-6ec5-459f-9397-79fbf147ddfe'	System	06 Sep 2020 19:07:17
User entered 'No (N)'	System	06 Sep 2020 19:07:17

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:42:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-06T12:07:14', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '07ffd07b-6ec5-459f-9397-79fbf147ddfe'	System	06 Sep 2020 19:07:17
User entered '06 Sep 2020 12:07'	System	06 Sep 2020 19:07:17

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 18:00:07

US3772187

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 18:00:07

US3772187

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 07:37:36
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:09:36
User entered 'Yes (Y)'	Sarah Sandberg (b) (4) (b) (4)	15 Sep 2020 17:20:32

US3772187

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 07:37:36
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:09:36
User entered '09 Sep 2020'	Sarah Sandberg (b) (4) (b) (4)	15 Sep 2020 17:20:32

US3772187

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 07:37:36
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:09:36
User entered 'Contact Made (CONTACT MADE)'	Sarah Sandberg (b) (4) (b) (4)	15 Sep 2020 17:20:32

US3772187

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 07:37:36
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:09:36
User entered empty.	Sarah Sandberg (b) (4) (b) (4)	15 Sep 2020 17:20:32

US3772187

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 07:37:42
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:09:42
User entered 'Yes (Y)'	Sarah Sandberg (b) (4) (b) (4)	15 Sep 2020 17:20:36

US3772187

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 07:37:42
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User entered '1'	System	15 Sep 2020 17:20:36

US3772187

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:00
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 07:37:19
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:10:41
User entered 'Yes (Y)'	Sarah Sandberg (b) (4) (b) (4)	15 Sep 2020 17:21:15

US3772187

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:00
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 07:37:19
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:10:41
User entered '15 Sep 2020'	Sarah Sandberg (b) (4) (b) (4)	15 Sep 2020 17:21:15

US3772187

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:00
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 07:37:19
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:10:41
User entered 'Contact Made (CONTACT MADE)'	Sarah Sandberg (b) (4) (b) (4)	15 Sep 2020 17:21:15

US3772187

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:00
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 07:37:19
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:10:41
User entered empty.	Sarah Sandberg (b) (4) (b) (4)	15 Sep 2020 17:21:15

US3772187

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:00
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 07:37:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:10:46
User entered 'Yes (Y)'	Sarah Sandberg (b) (4) (b) (4)	15 Sep 2020 17:21:19

US3772187

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:00
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 07:37:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:27:19
User entered '1'	System	15 Sep 2020 17:21:19

US3772187

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:11:53
User entered 'Yes (Y)'	Sarah Sandberg (b) (4) (b) (4)	22 Sep 2020 22:40:26

US3772187

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:11:53
User entered '22 Sep 2020'	Sarah Sandberg (b) (4) (b) (4)	22 Sep 2020 22:40:26

US3772187

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:11:53
User entered 'Contact Made (CONTACT MADE)'	Sarah Sandberg (b) (4) (b) (4)	22 Sep 2020 22:40:26

US3772187

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:21:12
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:11:53
User entered empty.	Sarah Sandberg (b) (4) (b) (4)	22 Sep 2020 22:40:26

US3772187

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:00
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:11:57
User entered 'Yes (Y)'	Sarah Sandberg (b) (4) (b) (4)	22 Sep 2020 22:40:30

US3772187

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:20:00
User entered '1'	System	22 Sep 2020 22:40:30

US3772187

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:21
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 17:49:36

US3772187

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:21
User entered '30 Sep 2020'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 17:49:36

US3772187

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:21
User entered 'Clinic (Clinic)'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 17:49:36

US3772187

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User entered 'VISIT2'	System	30 Sep 2020 17:49:36

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User accepted default value 'Pre-Dose (PREDOSE)'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:26
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:26
User entered '30 Sep 2020'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:26
User entered '09:43'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User entered '30 Sep 2020 09:43'	System	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:26
User entered '36.5' C	Emily Crews (b) (4) (b) (4)	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:26
User entered 'Oral (Oral)'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:26
User entered empty.	Emily Crews (b) (4) (b) (4)	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:26
User entered '68'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User entered 'bpm'	System	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:26
User entered '14'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User entered 'breaths/min'	System	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:26
User entered '108'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User entered 'mmHg'	System	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:26
User entered '78'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User entered 'mmHg'	System	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User accepted default value 'Post-Dose (POSTDOSE)'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:26
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 22:47:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 22:47:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	30 Sep 2020 22:47:43
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 22:47:38
User entered empty.	Emily Crews (b) (4) (b) (4)	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:26
User entered '30 Sep 2020'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:26
User entered '11:13'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User entered '30 Sep 2020 11:13'	System	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:26
User entered '36.7' C	Emily Crews (b) (4) (b) (4)	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:26
User entered 'Oral (Oral)'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:26
User entered empty.	Emily Crews (b) (4) (b) (4)	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:26
User entered '70'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User entered 'bpm'	System	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:26
User entered '15'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User entered 'breaths/min'	System	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:26
User entered '110'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User entered 'mmHg'	System	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:26
User entered '82'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User entered 'mmHg'	System	30 Sep 2020 22:47:38

US3772187

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:42:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:30
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 17:49:45

US3772187

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:42:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:30
User entered '30 Sep 2020'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 17:49:45

US3772187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:35
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 17:50:40

US3772187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:35
User entered empty.	Emily Crews (b) (4) (b) (4)	30 Sep 2020 17:50:40

US3772187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:35
User entered empty.	Emily Crews (b) (4) (b) (4)	30 Sep 2020 17:50:40

US3772187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User entered 'MRNA-1273 OR PLACEBO'	System	30 Sep 2020 17:50:40

US3772187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:35
User entered '30 Sep 2020'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 17:50:40

US3772187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:35
User entered '10:41'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 17:50:40

US3772187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User entered '30 Sep 2020 10:41'	System	30 Sep 2020 17:50:40

US3772187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:35
User entered 'Left Arm (LEFT ARM)'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 17:50:40

US3772187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 21:12:35
User entered 'ONCE'	System	30 Sep 2020 17:50:40

US3772187

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User entered 'INTRAMUSCULAR'	System	30 Sep 2020 17:50:40

US3772187

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:42:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:43:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
User closed query 'Per GCL Lab Reconciliation: Re-Query 2: Immunogenicity: Thank you for your response, Please ship all the sample when the issue resolves. Also keep the query open until all the samples have been shipped and provide the details of the shipping in the response.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 10:57:35
Query 'Per GCL Lab Reconciliation: Re-Query 2: Immunogenicity: Thank you for your response, Please ship all the sample when the issue resolves. Also keep the query open until all the samples have been shipped and provide the details of the shipping in the response.' answered with 'Sent 23Nov2020 TRK# 933677685650' (Site from DM).	Marisol Corrales (b) (4) (b) (4)	23 Dec 2020 22:48:00
User opened query 'Per GCL Lab Reconciliation: Re-Query 2: Immunogenicity: Thank you for your response, Please ship all the sample when the issue resolves. Also keep the query open until all the samples have been shipped and provide the details of the shipping in the response.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 12:04:15
User closed query 'Per GCL Lab Reconciliation: Re-Query: Please confirm the shipping information as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 12:04:15
Query 'Per GCL Lab Reconciliation: Re-Query: Please confirm the shipping information as appropriate.' answered with 'Remaining samples will be shipped when site receives shipping material from PPD' (Site from DM).	Emily Crews (b) (4) (b) (4)	08 Dec 2020 19:09:54
User opened query 'Per GCL Lab Reconciliation: Re-Query: Please confirm the shipping information as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 16:38:47
User closed query 'Per GCL Lab Reconciliation: Re-query: Please clarify if the sample was ever shipped to GCL, because this sample still does not exist in the GCL database, and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 15:56:44

US3772187

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:42:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Re-query: Please clarify if the sample was ever shipped to GCL, because this sample still does not exist in the GCL database, and update if appropriate.' answered with 'Samples have been sent from site' (Site from DM).	Emily Crews (b) (4)	04 Dec 2020 21:33:00
User opened query 'Per GCL Lab Reconciliation: Re-query: Please clarify if the sample was ever shipped to GCL, because this sample still does not exist in the GCL database, and update if appropriate.' (Site from DM).	(b) (4)	
User closed query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 2 Day 29 with a Collection Date of 30SEP2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 21:41:48
Query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 2 Day 29 with a Collection Date of 30SEP2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate.' answered with 'Stored on site' (Site from DM).	Emily Crews (b) (4)	05 Nov 2020 23:12:37
User opened query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 2 Day 29 with a Collection Date of 30SEP2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 17:18:12
User entered 'Yes (Y)'	Emily Crews (b) (4)	30 Sep 2020 17:49:59
	(b) (4)	

US3772187

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:42:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:43
User entered '30 Sep 2020'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 17:49:59

US3772187

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:42:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:45
User entered '10:14'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 17:49:59

US3772187

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:42:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User entered '30 Sep 2020 10:14'	System	30 Sep 2020 17:49:59

US3772187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:42:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:54
User entered '30 Sep 2020'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 17:50:16

US3772187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:42:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 17:50:16

US3772187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:42:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:54
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 17:50:16

US3772187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:42:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:54
User entered '10:18'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 17:50:16

US3772187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:42:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User entered '30 Sep 2020 10:18'	System	30 Sep 2020 17:50:16

US3772187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:42:05

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 17:50:16

US3772187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:42:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:54
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 17:50:16

US3772187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:42:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:12:54
User entered empty.	Emily Crews (b) (4) (b) (4)	30 Sep 2020 17:50:16

US3772187

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:42:05

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User entered empty.	System	30 Sep 2020 17:50:16

US3772187

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:13:01
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	30 Sep 2020 17:50:22

US3772187

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User entered '1'	System	30 Sep 2020 17:50:22

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	30 Sep 2020 17:50:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T11:12:52', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'ee5097f8-ca35-4a13-bec9-3d1466d03de9'	System	30 Sep 2020 18:13:28
User entered 'Yes (Y)'	System	30 Sep 2020 18:13:28

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T11:12:55', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'ee5097f8-ca35-4a13-bec9-3d1466d03de9' User entered '98.1'	System	30 Sep 2020 18:13:28
	System	30 Sep 2020 18:13:28

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T11:13:01', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'ee5097f8-ca35-4a13-bec9-3d1466d03de9'	System	30 Sep 2020 18:13:28
User entered 'No (N)'	System	30 Sep 2020 18:13:28

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T11:13:25', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'ee5097f8-ca35-4a13-bec9-3d1466d03de9'	System	30 Sep 2020 18:13:28
User entered '30 Sep 2020 11:13'	System	30 Sep 2020 18:13:28

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '30 Sep 2020 11:01'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '30 Sep 2020 13:31'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	30 Sep 2020 17:50:40
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T20:43:39', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '6732a5ae-7313-4a1f-a2f0-393edd4d1303'	System	01 Oct 2020 03:45:14
User entered 'Yes (Y)'	System	01 Oct 2020 03:45:14

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T20:44:56', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '6732a5ae-7313-4a1f-a2f0-393edd4d1303'	System	01 Oct 2020 03:45:14
User entered '98.4'	System	01 Oct 2020 03:45:14

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T20:45:08', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '6732a5ae-7313-4a1f-a2f0-393edd4d1303'	System	01 Oct 2020 03:45:14
User entered 'No (N)'	System	01 Oct 2020 03:45:14

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T20:45:11', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '6732a5ae-7313-4a1f-a2f0-393edd4d1303'	System	01 Oct 2020 03:45:14
User entered '30 Sep 2020 20:45'	System	01 Oct 2020 03:45:14

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '30 Sep 2020 14:26'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	30 Sep 2020 17:50:40
User entered 'Day 2'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:42:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-01T15:00:04', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '34004f8c-d7b8-4cf8-8a05-f577943232f2'	System	01 Oct 2020 22:01:20
User entered 'Yes (Y)'	System	01 Oct 2020 22:01:20

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:42:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-01T15:00:59', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '34004f8c-d7b8-4cf8-8a05-f577943232f2'	System	01 Oct 2020 22:01:20
User entered '98.0'	System	01 Oct 2020 22:01:20

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-01T15:01:10', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '34004f8c-d7b8-4cf8-8a05-f577943232f2'	System	01 Oct 2020 22:01:20
User entered 'No (N)'	System	01 Oct 2020 22:01:20

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-01T15:01:14', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '34004f8c-d7b8-4cf8-8a05-f577943232f2'	System	01 Oct 2020 22:01:20
User entered '01 Oct 2020 15:01'	System	01 Oct 2020 22:01:20

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	30 Sep 2020 17:50:40
User entered 'Day 3'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:42:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-02T16:05:03', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '30de550d-6111-40ab-87b0-4ea941aa9520'	System	02 Oct 2020 23:05:22
User entered 'Yes (Y)'	System	02 Oct 2020 23:05:22

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:42:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-02T16:05:08', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '30de550d-6111-40ab-87b0-4ea941aa9520' User entered '98.1'	System	02 Oct 2020 23:05:22
	System	02 Oct 2020 23:05:22

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-02T16:05:11', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '30de550d-6111-40ab-87b0-4ea941aa9520'	System	02 Oct 2020 23:05:22
User entered 'Yes (Y)'	System	02 Oct 2020 23:05:22

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
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 'Subject contacted.' (Site from System).	(b) (4), (b) (6)	08 Oct 2020 11:58:33
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	07 Oct 2020 19:22:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-02T16:05:17', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '30de550d-6111-40ab-87b0-4ea941aa9520'	System	02 Oct 2020 23:05:22
User entered '1'	System	02 Oct 2020 23:05:22

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:42:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-02T16:05:17', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '30de550d-6111-40ab-87b0-4ea941aa9520'	System	02 Oct 2020 23:05:22
User entered '0'	System	02 Oct 2020 23:05:22

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-02T16:05:19', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '30de550d-6111-40ab-87b0-4ea941aa9520'	System	02 Oct 2020 23:05:22
User entered '02 Oct 2020 16:05'	System	02 Oct 2020 23:05:22

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	30 Sep 2020 17:50:40
User entered 'Day 4'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:42:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-03T16:16:39', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '4437c842-c236-4e2a-9a8e-f4c9a7de3cb1'	System	03 Oct 2020 23:16:52
User entered 'Yes (Y)'	System	03 Oct 2020 23:16:52

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:42:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-03T16:16:43', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '4437c842-c236-4e2a-9a8e-f4c9a7de3cb1'	System	03 Oct 2020 23:16:52
User entered '98.0'	System	03 Oct 2020 23:16:52

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-03T16:16:46', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '4437c842-c236-4e2a-9a8e-f4c9a7de3cb1'	System	03 Oct 2020 23:16:52
User entered 'No (N)'	System	03 Oct 2020 23:16:52

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-03T16:16:49', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '4437c842-c236-4e2a-9a8e-f4c9a7de3cb1'	System	03 Oct 2020 23:16:52
User entered '03 Oct 2020 16:16'	System	03 Oct 2020 23:16:52

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	30 Sep 2020 17:50:40
User entered 'Day 5'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:42:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-04T22:27:50', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '7371d64e-26d8-458c-a096-423bdf969de5'	System	05 Oct 2020 05:28:05
User entered 'Yes (Y)'	System	05 Oct 2020 05:28:05

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:42:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-04T22:27:54', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '7371d64e-26d8-458c-a096-423bdf969de5'	System	05 Oct 2020 05:28:05
User entered '98.0'	System	05 Oct 2020 05:28:05

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-04T22:27:57', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '7371d64e-26d8-458c-a096-423bdf969de5'	System	05 Oct 2020 05:28:05
User entered 'No (N)'	System	05 Oct 2020 05:28:05

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-04T22:27:59', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '7371d64e-26d8-458c-a096-423bdf969de5'	System	05 Oct 2020 05:28:05
User entered '04 Oct 2020 22:27'	System	05 Oct 2020 05:28:05

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	30 Sep 2020 17:50:40
User entered 'Day 6'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:42:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-05T17:03:11', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'a854767d-a591-4080-9b20-400083a81e92'	System	06 Oct 2020 00:03:25
User entered 'Yes (Y)'	System	06 Oct 2020 00:03:25

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:42:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-05T17:03:15', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'a854767d-a591-4080-9b20-400083a81e92'	System	06 Oct 2020 00:03:25
User entered '98.3'	System	06 Oct 2020 00:03:25

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-05T17:03:17', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'a854767d-a591-4080-9b20-400083a81e92'	System	06 Oct 2020 00:03:25
User entered 'No (N)'	System	06 Oct 2020 00:03:25

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-05T17:03:20', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'a854767d-a591-4080-9b20-400083a81e92'	System	06 Oct 2020 00:03:25
User entered '05 Oct 2020 17:03'	System	06 Oct 2020 00:03:25

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	30 Sep 2020 17:50:40
User entered 'Day 7'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:42:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-06T14:43:02', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '97d77ff2-4afe-4b88-aa51-5d54764d284b'	System	06 Oct 2020 21:43:50
User entered 'Yes (Y)'	System	06 Oct 2020 21:43:50

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:42:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-06T14:43:39', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '97d77ff2-4afe-4b88-aa51-5d54764d284b'	System	06 Oct 2020 21:43:50
User entered '98.1'	System	06 Oct 2020 21:43:50

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-06T14:43:44', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '97d77ff2-4afe-4b88-aa51-5d54764d284b'	System	06 Oct 2020 21:43:50
User entered 'No (N)'	System	06 Oct 2020 21:43:50

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-06T14:43:46', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '97d77ff2-4afe-4b88-aa51-5d54764d284b' User entered '06 Oct 2020 14:43'	System	06 Oct 2020 21:43:50
	System	06 Oct 2020 21:43:50

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	30 Sep 2020 17:50:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T11:13:38', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '747191d6-4cbb-460a-989a-9cc063d22b7a'	System	30 Sep 2020 18:14:17
User entered 'None (1)'	System	30 Sep 2020 18:14:17

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T11:13:54', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '747191d6-4cbb-460a-989a-9cc063d22b7a'	System	30 Sep 2020 18:14:17
User entered 'No (N)'	System	30 Sep 2020 18:14:17

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T11:14:02', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '747191d6-4cbb-460a-989a-9cc063d22b7a'	System	30 Sep 2020 18:14:17
User entered 'No (N)'	System	30 Sep 2020 18:14:17

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T11:14:10', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '747191d6-4cbb-460a-989a-9cc063d22b7a'	System	30 Sep 2020 18:14:17
User entered 'None (1)'	System	30 Sep 2020 18:14:17

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T11:14:15', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '747191d6-4cbb-460a-989a-9cc063d22b7a'	System	30 Sep 2020 18:14:17
User entered '30 Sep 2020 11:14'	System	30 Sep 2020 18:14:17

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '30 Sep 2020 11:01'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '30 Sep 2020 13:31'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	30 Sep 2020 17:50:40
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T20:45:15', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '05a43fe4-1988-4a34-ae0f-51b209c3c221'	System	01 Oct 2020 03:45:42
User entered 'None (1)'	System	01 Oct 2020 03:45:42

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T20:45:18', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '05a43fe4-1988-4a34-ae0f-51b209c3c221'	System	01 Oct 2020 03:45:42
User entered 'No (N)'	System	01 Oct 2020 03:45:42

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T20:45:30', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '05a43fe4-1988-4a34-ae0f-51b209c3c221'	System	01 Oct 2020 03:45:42
User entered 'No (N)'	System	01 Oct 2020 03:45:42

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T20:45:37', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '05a43fe4-1988-4a34-ae0f-51b209c3c221'	System	01 Oct 2020 03:45:42
User entered 'None (1)'	System	01 Oct 2020 03:45:42

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T20:45:39', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '05a43fe4-1988-4a34-ae0f-51b209c3c221'	System	01 Oct 2020 03:45:42
User entered '30 Sep 2020 20:45'	System	01 Oct 2020 03:45:42

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '30 Sep 2020 14:26'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	30 Sep 2020 17:50:40
User entered 'Day 2'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-01T15:01:19', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '43b2848a-3607-495d-b29f-6b3353f11912'	System	01 Oct 2020 22:01:45
User entered 'None (1)'	System	01 Oct 2020 22:01:45

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-01T15:01:21', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '43b2848a-3607-495d-b29f-6b3353f11912'	System	01 Oct 2020 22:01:45
User entered 'No (N)'	System	01 Oct 2020 22:01:45

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-01T15:01:23', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '43b2848a-3607-495d-b29f-6b3353f11912'	System	01 Oct 2020 22:01:45
User entered 'No (N)'	System	01 Oct 2020 22:01:45

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-01T15:01:40', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '43b2848a-3607-495d-b29f-6b3353f11912'	System	01 Oct 2020 22:01:45
User entered 'None (1)'	System	01 Oct 2020 22:01:45

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-01T15:01:43', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '43b2848a-3607-495d-b29f-6b3353f11912'	System	01 Oct 2020 22:01:45
User entered '01 Oct 2020 15:01'	System	01 Oct 2020 22:01:45

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	30 Sep 2020 17:50:40
User entered 'Day 3'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-02T16:05:23', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '4b7e86dd-f743-44f2-8461-ce8d20618c00'	System	02 Oct 2020 23:05:38
User entered 'None (1)'	System	02 Oct 2020 23:05:38

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-02T16:05:25', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '4b7e86dd-f743-44f2-8461-ce8d20618c00'	System	02 Oct 2020 23:05:38
User entered 'No (N)'	System	02 Oct 2020 23:05:38

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-02T16:05:27', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '4b7e86dd-f743-44f2-8461-ce8d20618c00'	System	02 Oct 2020 23:05:38
User entered 'No (N)'	System	02 Oct 2020 23:05:38

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-02T16:05:29', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '4b7e86dd-f743-44f2-8461-ce8d20618c00'	System	02 Oct 2020 23:05:38
User entered 'None (1)'	System	02 Oct 2020 23:05:38

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-02T16:05:31', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '4b7e86dd-f743-44f2-8461-ce8d20618c00'	System	02 Oct 2020 23:05:38
User entered '02 Oct 2020 16:05'	System	02 Oct 2020 23:05:38

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	30 Sep 2020 17:50:40
User entered 'Day 4'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-03T16:17:05', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '05afd23e-876e-449b-bd0e-45125de85931'	System	03 Oct 2020 23:17:18
User entered 'None (1)'	System	03 Oct 2020 23:17:18

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-03T16:17:09', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '05afd23e-876e-449b-bd0e-45125de85931'	System	03 Oct 2020 23:17:18
User entered 'No (N)'	System	03 Oct 2020 23:17:18

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-03T16:17:11', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '05afd23e-876e-449b-bd0e-45125de85931'	System	03 Oct 2020 23:17:18
User entered 'No (N)'	System	03 Oct 2020 23:17:18

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-03T16:17:13', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '05afd23e-876e-449b-bd0e-45125de85931'	System	03 Oct 2020 23:17:18
User entered 'None (1)'	System	03 Oct 2020 23:17:18

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-03T16:17:15', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '05afd23e-876e-449b-bd0e-45125de85931'	System	03 Oct 2020 23:17:18
User entered '03 Oct 2020 16:17'	System	03 Oct 2020 23:17:18

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	30 Sep 2020 17:50:40
User entered 'Day 5'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-04T22:28:02', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '8d26a0ff-fbb6-4d80-99b7-5c0ba629bdc6'	System	05 Oct 2020 05:28:15
User entered 'None (1)'	System	05 Oct 2020 05:28:15

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-04T22:28:04', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '8d26a0ff-fbb6-4d80-99b7-5c0ba629bdc6'	System	05 Oct 2020 05:28:15
User entered 'No (N)'	System	05 Oct 2020 05:28:15

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-04T22:28:06', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '8d26a0ff-fbb6-4d80-99b7-5c0ba629bdc6'	System	05 Oct 2020 05:28:15
User entered 'No (N)'	System	05 Oct 2020 05:28:15

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-04T22:28:08', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '8d26a0ff-fbb6-4d80-99b7-5c0ba629bdc6'	System	05 Oct 2020 05:28:15
User entered 'None (1)'	System	05 Oct 2020 05:28:15

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-04T22:28:10', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '8d26a0ff-fbb6-4d80-99b7-5c0ba629bdc6'	System	05 Oct 2020 05:28:15
User entered '04 Oct 2020 22:28'	System	05 Oct 2020 05:28:15

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	30 Sep 2020 17:50:40
User entered 'Day 6'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-05T17:03:23', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'c9e5fad3-4513-48e4-81ac-ab9549c24f97'	System	06 Oct 2020 00:03:36
User entered 'None (1)'	System	06 Oct 2020 00:03:36

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-05T17:03:25', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'c9e5fad3-4513-48e4-81ac-ab9549c24f97'	System	06 Oct 2020 00:03:36
User entered 'No (N)'	System	06 Oct 2020 00:03:36

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-05T17:03:27', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'c9e5fad3-4513-48e4-81ac-ab9549c24f97'	System	06 Oct 2020 00:03:36
User entered 'No (N)'	System	06 Oct 2020 00:03:36

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-05T17:03:28', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'c9e5fad3-4513-48e4-81ac-ab9549c24f97'	System	06 Oct 2020 00:03:36
User entered 'None (1)'	System	06 Oct 2020 00:03:36

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-05T17:03:30', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'c9e5fad3-4513-48e4-81ac-ab9549c24f97'	System	06 Oct 2020 00:03:36
User entered '05 Oct 2020 17:03'	System	06 Oct 2020 00:03:36

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	30 Sep 2020 17:50:40
User entered 'Day 7'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-06T14:43:50', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '735d02e0-366f-4a67-b897-bc484b38fe8f'	System	06 Oct 2020 21:44:02
User entered 'None (1)'	System	06 Oct 2020 21:44:02

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-06T14:43:52', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '735d02e0-366f-4a67-b897-bc484b38fe8f'	System	06 Oct 2020 21:44:02
User entered 'No (N)'	System	06 Oct 2020 21:44:02

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-06T14:43:55', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '735d02e0-366f-4a67-b897-bc484b38fe8f'	System	06 Oct 2020 21:44:02
User entered 'No (N)'	System	06 Oct 2020 21:44:02

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-06T14:43:57', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '735d02e0-366f-4a67-b897-bc484b38fe8f'	System	06 Oct 2020 21:44:02
User entered 'None (1)'	System	06 Oct 2020 21:44:02

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:42:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-06T14:43:59', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '735d02e0-366f-4a67-b897-bc484b38fe8f' User entered '06 Oct 2020 14:43'	System	06 Oct 2020 21:44:02
	System	06 Oct 2020 21:44:02

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	30 Sep 2020 17:50:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T11:14:23', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'b97adf12-f133-4272-9e08-fc49113e0e5d'	System	30 Sep 2020 18:14:45
User entered 'None (0)'	System	30 Sep 2020 18:14:45

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T11:14:28', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'b97adf12-f133-4272-9e08-fc49113e0e5d'	System	30 Sep 2020 18:14:45
User entered 'None (0)'	System	30 Sep 2020 18:14:45

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T11:14:31', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'b97adf12-f133-4272-9e08-fc49113e0e5d'	System	30 Sep 2020 18:14:45
User entered 'None (0)'	System	30 Sep 2020 18:14:45

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T11:14:34', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'b97adf12-f133-4272-9e08-fc49113e0e5d'	System	30 Sep 2020 18:14:45
User entered 'None (0)'	System	30 Sep 2020 18:14:45

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T11:14:36', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'b97adf12-f133-4272-9e08-fc49113e0e5d'	System	30 Sep 2020 18:14:45
User entered 'None (0)'	System	30 Sep 2020 18:14:45

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T11:14:37', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'b97adf12-f133-4272-9e08-fc49113e0e5d'	System	30 Sep 2020 18:14:45
User entered 'None (0)'	System	30 Sep 2020 18:14:45

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T11:14:40', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'b97adf12-f133-4272-9e08-fc49113e0e5d'	System	30 Sep 2020 18:14:45
User entered 'No (N)'	System	30 Sep 2020 18:14:45

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T11:14:43', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'b97adf12-f133-4272-9e08-fc49113e0e5d'	System	30 Sep 2020 18:14:45
User entered '30 Sep 2020 11:14'	System	30 Sep 2020 18:14:45

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '30 Sep 2020 11:01'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '30 Sep 2020 13:31'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	30 Sep 2020 17:50:40
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T20:45:46', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '6c5da317-3372-4cab-8e50-cda33c3cfae0'	System	01 Oct 2020 03:46:11
User entered 'None (0)'	System	01 Oct 2020 03:46:11

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T20:45:51', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '6c5da317-3372-4cab-8e50-cda33c3cfae0'	System	01 Oct 2020 03:46:11
User entered 'None (0)'	System	01 Oct 2020 03:46:11

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T20:45:53', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '6c5da317-3372-4cab-8e50-cda33c3cfae0'	System	01 Oct 2020 03:46:11
User entered 'None (0)'	System	01 Oct 2020 03:46:11

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T20:45:55', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '6c5da317-3372-4cab-8e50-cda33c3cfae0'	System	01 Oct 2020 03:46:11
User entered 'None (0)'	System	01 Oct 2020 03:46:11

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T20:45:56', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '6c5da317-3372-4cab-8e50-cda33c3cfae0'	System	01 Oct 2020 03:46:11
User entered 'None (0)'	System	01 Oct 2020 03:46:11

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T20:45:58', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '6c5da317-3372-4cab-8e50-cda33c3cfae0'	System	01 Oct 2020 03:46:11
User entered 'None (0)'	System	01 Oct 2020 03:46:11

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T20:46:03', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '6c5da317-3372-4cab-8e50-cda33c3cfae0'	System	01 Oct 2020 03:46:11
User entered 'No (N)'	System	01 Oct 2020 03:46:11

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-09-30T20:46:05', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '6c5da317-3372-4cab-8e50-cda33c3cfae0'	System	01 Oct 2020 03:46:11
User entered '30 Sep 2020 20:46'	System	01 Oct 2020 03:46:11

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '30 Sep 2020 14:26'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	30 Sep 2020 17:50:40
User entered 'Day 2'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:42:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-01T15:01:51', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'b02a7e00-d6a2-44ee-9b29-ce53f53baf9b'	System	01 Oct 2020 22:02:10
User entered 'No interference with activity (1)'	System	01 Oct 2020 22:02:10

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:42:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-01T15:01:54', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'b02a7e00-d6a2-44ee-9b29-ce53f53baf9b'	System	01 Oct 2020 22:02:10
User entered 'None (0)'	System	01 Oct 2020 22:02:10

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:42:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-01T15:01:56', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'b02a7e00-d6a2-44ee-9b29-ce53f53baf9b'	System	01 Oct 2020 22:02:10
User entered 'None (0)'	System	01 Oct 2020 22:02:10

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:42:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-01T15:01:57', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'b02a7e00-d6a2-44ee-9b29-ce53f53baf9b'	System	01 Oct 2020 22:02:10
User entered 'None (0)'	System	01 Oct 2020 22:02:10

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:42:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-01T15:01:59', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'b02a7e00-d6a2-44ee-9b29-ce53f53baf9b'	System	01 Oct 2020 22:02:10
User entered 'None (0)'	System	01 Oct 2020 22:02:10

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:42:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-01T15:02:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'b02a7e00-d6a2-44ee-9b29-ce53f53baf9b'	System	01 Oct 2020 22:02:10
User entered 'None (0)'	System	01 Oct 2020 22:02:10

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-01T15:02:03', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'b02a7e00-d6a2-44ee-9b29-ce53f53baf9b'	System	01 Oct 2020 22:02:10
User entered 'No (N)'	System	01 Oct 2020 22:02:10

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:42:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-01T15:02:05', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'b02a7e00-d6a2-44ee-9b29-ce53f53baf9b'	System	01 Oct 2020 22:02:10
User entered '01 Oct 2020 15:02'	System	01 Oct 2020 22:02:10

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	30 Sep 2020 17:50:40
User entered 'Day 3'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:42:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-02T16:05:50', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '86e258a1-d0b6-46f8-9f97-01112fa0ec01'	System	02 Oct 2020 23:06:22
User entered 'No interference with activity (1)'	System	02 Oct 2020 23:06:22

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:42:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-02T16:06:03', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '86e258a1-d0b6-46f8-9f97-01112fa0ec01'	System	02 Oct 2020 23:06:22
User entered 'Some interference with activity (2)'	System	02 Oct 2020 23:06:22

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:42:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-02T16:06:05', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '86e258a1-d0b6-46f8-9f97-01112fa0ec01'	System	02 Oct 2020 23:06:22
User entered 'None (0)'	System	02 Oct 2020 23:06:22

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:42:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-02T16:06:08', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '86e258a1-d0b6-46f8-9f97-01112fa0ec01'	System	02 Oct 2020 23:06:22
User entered 'None (0)'	System	02 Oct 2020 23:06:22

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:42:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-02T16:06:10', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '86e258a1-d0b6-46f8-9f97-01112fa0ec01'	System	02 Oct 2020 23:06:22
User entered 'None (0)'	System	02 Oct 2020 23:06:22

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:42:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-02T16:06:12', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '86e258a1-d0b6-46f8-9f97-01112fa0ec01'	System	02 Oct 2020 23:06:22
User entered 'None (0)'	System	02 Oct 2020 23:06:22

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-02T16:06:15', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '86e258a1-d0b6-46f8-9f97-01112fa0ec01'	System	02 Oct 2020 23:06:22
User entered 'No (N)'	System	02 Oct 2020 23:06:22

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:42:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-02T16:06:17', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '86e258a1-d0b6-46f8-9f97-01112fa0ec01'	System	02 Oct 2020 23:06:22
User entered '02 Oct 2020 16:06'	System	02 Oct 2020 23:06:22

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	30 Sep 2020 17:50:40
User entered 'Day 4'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:42:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-03T16:17:51', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '975a53c3-abda-4262-9f06-8b8c0adf3c'	System	03 Oct 2020 23:18:10
User entered 'No interference with activity (1)'	System	03 Oct 2020 23:18:10

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:42:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-03T16:17:53', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '975a53c3-abda-4262-9f06-8b8c0adf3c'	System	03 Oct 2020 23:18:10
User entered 'None (0)'	System	03 Oct 2020 23:18:10

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:42:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-03T16:17:57', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '975a53c3-abda-4262-9f06-8b8c0adf3c'	System	03 Oct 2020 23:18:10
User entered 'None (0)'	System	03 Oct 2020 23:18:10

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:42:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-03T16:17:59', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '975a53c3-abda-4262-9f06-8b8c0adf3c'	System	03 Oct 2020 23:18:10
User entered 'None (0)'	System	03 Oct 2020 23:18:10

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:42:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-03T16:18:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '975a53c3-abda-4262-9f06-8b8c0adf3c'	System	03 Oct 2020 23:18:10
User entered 'None (0)'	System	03 Oct 2020 23:18:10

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:42:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-03T16:18:01', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '975a53c3-abda-4262-9f06-8b8c0adf3c'	System	03 Oct 2020 23:18:10
User entered 'None (0)'	System	03 Oct 2020 23:18:10

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-03T16:18:03', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '975a53c3-abda-4262-9f06-8b8c0adf3c'	System	03 Oct 2020 23:18:10
User entered 'No (N)'	System	03 Oct 2020 23:18:10

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:42:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-03T16:18:06', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '975a53c3-abda-4262-9f06-8b8c0adf3c'	System	03 Oct 2020 23:18:10
User entered '03 Oct 2020 16:18'	System	03 Oct 2020 23:18:10

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	30 Sep 2020 17:50:40
User entered 'Day 5'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:42:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-04T22:28:14', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '7011f8dd-87d9-4fbc-82e2-26bfd3dbbc55'	System	05 Oct 2020 05:28:31
User entered 'None (0)'	System	05 Oct 2020 05:28:31

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:42:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-04T22:28:15', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '7011f8dd-87d9-4fbc-82e2-26bfd3dbbc55'	System	05 Oct 2020 05:28:31
User entered 'None (0)'	System	05 Oct 2020 05:28:31

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:42:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-04T22:28:16', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '7011f8dd-87d9-4fbc-82e2-26bfd3dbbc55'	System	05 Oct 2020 05:28:31
User entered 'None (0)'	System	05 Oct 2020 05:28:31

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:42:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-04T22:28:17', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '7011f8dd-87d9-4fbc-82e2-26bfd3dbbc55'	System	05 Oct 2020 05:28:31
User entered 'None (0)'	System	05 Oct 2020 05:28:31

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:42:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-04T22:28:18', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '7011f8dd-87d9-4fbc-82e2-26bfd3dbbc55'	System	05 Oct 2020 05:28:31
User entered 'None (0)'	System	05 Oct 2020 05:28:31

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:42:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-04T22:28:20', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '7011f8dd-87d9-4fbc-82e2-26bfd3dbbc55'	System	05 Oct 2020 05:28:31
User entered 'None (0)'	System	05 Oct 2020 05:28:31

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-04T22:28:24', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '7011f8dd-87d9-4fbe-82e2-26bfd3dbbc55'	System	05 Oct 2020 05:28:31
User entered 'No (N)'	System	05 Oct 2020 05:28:31

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:42:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-04T22:28:26', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '7011f8dd-87d9-4fbe-82e2-26bfd3dbbc55'	System	05 Oct 2020 05:28:31
User entered '04 Oct 2020 22:28'	System	05 Oct 2020 05:28:31

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	30 Sep 2020 17:50:40
User entered 'Day 6'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:42:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-05T17:03:37', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '383af13f-58ad-4bc7-acc9-c170e9e9874d'	System	06 Oct 2020 00:03:50
User entered 'None (0)'	System	06 Oct 2020 00:03:50

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:42:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-05T17:03:38', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '383af13f-58ad-4bc7-acc9-c170e9e9874d'	System	06 Oct 2020 00:03:50
User entered 'None (0)'	System	06 Oct 2020 00:03:50

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:42:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-05T17:03:39', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '383af13f-58ad-4bc7-acc9-c170e9e9874d'	System	06 Oct 2020 00:03:50
User entered 'None (0)'	System	06 Oct 2020 00:03:50

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:42:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-05T17:03:41', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '383af13f-58ad-4bc7-acc9-c170e9e9874d'	System	06 Oct 2020 00:03:50
User entered 'None (0)'	System	06 Oct 2020 00:03:50

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:42:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-05T17:03:42', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '383af13f-58ad-4bc7-acc9-c170e9e9874d'	System	06 Oct 2020 00:03:50
User entered 'None (0)'	System	06 Oct 2020 00:03:50

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:42:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-05T17:03:43', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '383af13f-58ad-4bc7-acc9-c170e9e9874d'	System	06 Oct 2020 00:03:50
User entered 'None (0)'	System	06 Oct 2020 00:03:50

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-05T17:03:45', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '383af13f-58ad-4bc7-acc9-c170e9e9874d'	System	06 Oct 2020 00:03:50
User entered 'No (N)'	System	06 Oct 2020 00:03:50

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:42:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-05T17:03:47', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '383af13f-58ad-4bc7-acc9-c170e9e9874d' User entered '05 Oct 2020 17:03'	System	06 Oct 2020 00:03:50
	System	06 Oct 2020 00:03:50

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	30 Sep 2020 17:50:40
User entered 'Day 7'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:42:05

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-06T14:44:02', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '01fd1506-646f-4c3a-b6f3-09f0c21f1245'	System	06 Oct 2020 21:44:19
User entered 'None (0)'	System	06 Oct 2020 21:44:19

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:42:05

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-06T14:44:03', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '01fd1506-646f-4c3a-b6f3-09f0c21f1245'	System	06 Oct 2020 21:44:19
User entered 'None (0)'	System	06 Oct 2020 21:44:19

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:42:05

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-06T14:44:04', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '01fd1506-646f-4c3a-b6f3-09f0c21f1245'	System	06 Oct 2020 21:44:19
User entered 'None (0)'	System	06 Oct 2020 21:44:19

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:42:05

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-06T14:44:06', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '01fd1506-646f-4c3a-b6f3-09f0c21f1245'	System	06 Oct 2020 21:44:19
User entered 'None (0)'	System	06 Oct 2020 21:44:19

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:42:05

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-06T14:44:07', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '01fd1506-646f-4c3a-b6f3-09f0c21f1245'	System	06 Oct 2020 21:44:19
User entered 'None (0)'	System	06 Oct 2020 21:44:19

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:42:05

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-06T14:44:09', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '01fd1506-646f-4c3a-b6f3-09f0c21f1245'	System	06 Oct 2020 21:44:19
User entered 'None (0)'	System	06 Oct 2020 21:44:19

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:42:05

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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-06T14:44:11', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '01fd1506-646f-4c3a-b6f3-09f0c21f1245'	System	06 Oct 2020 21:44:19
User entered 'No (N)'	System	06 Oct 2020 21:44:19

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:42:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-10-06T14:44:13', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '01fd1506-646f-4c3a-b6f3-09f0c21f1245'	System	06 Oct 2020 21:44:19
User entered '06 Oct 2020 14:44'	System	06 Oct 2020 21:44:19

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:42:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 17:50:40

US3772187

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:42:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 17:50:40

US3772187

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:43:36
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:33:35

US3772187

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:43:36
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:33:35

US3772187

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:43:36
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:33:35

US3772187

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:43:36
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:33:35

US3772187

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:43:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:33:39

US3772187

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User entered '1'	System	07 Oct 2020 19:33:39

US3772187

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:10:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 22:39:57

US3772187

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:10:08
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 22:39:57

US3772187

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:10:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Oct 2020 22:39:57

US3772187

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:10:08
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 22:39:57

US3772187

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:10:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 22:40:01

US3772187

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User entered '1'	System	14 Oct 2020 22:40:01

US3772187

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:11:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 18:06:56

US3772187

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:11:14
User entered '21 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 18:06:56

US3772187

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:11:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Oct 2020 18:06:56

US3772187

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:11:14
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 18:06:56

US3772187

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:11:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 18:07:01

US3772187

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User entered '1'	System	21 Oct 2020 18:07:01

US3772187

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:43:58
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	02 Nov 2020 23:27:32

US3772187

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:43:58
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
User entered '02 Nov 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	02 Nov 2020 23:27:32

US3772187

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:43:58
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
User entered 'Clinic (Clinic)'	(b) (4) Emily Crews (b) (4) (b) (4)	02 Nov 2020 23:27:32

US3772187

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User entered 'VISIT3'	System	02 Nov 2020 23:27:32

US3772187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:44:02
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	02 Nov 2020 23:28:46

US3772187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:44:02
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
User entered '02 Nov 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	02 Nov 2020 23:28:46

US3772187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:44:02
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
User entered '10:30'	(b) (4) Emily Crews (b) (4) (b) (4)	02 Nov 2020 23:28:46

US3772187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:22
User entered '02 Nov 2020 10:30'	System	02 Nov 2020 23:28:46

US3772187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:44:02
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
User entered '36.4' C	(b) (4) Emily Crews (b) (4) (b) (4)	02 Nov 2020 23:28:46

US3772187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:44:02
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
User entered 'Oral (Oral)'	(b) (4) Emily Crews (b) (4) (b) (4)	02 Nov 2020 23:28:46

US3772187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:44:02
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	02 Nov 2020 23:28:46

US3772187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:44:02
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
User entered '65'	(b) (4) Emily Crews (b) (4) (b) (4)	02 Nov 2020 23:28:46

US3772187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:22
User entered 'bpm'	System	02 Nov 2020 23:28:46

US3772187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:44:02
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
User entered '18'	(b) (4) Emily Crews (b) (4) (b) (4)	02 Nov 2020 23:28:46

US3772187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:22
User entered 'breaths/min'	System	02 Nov 2020 23:28:46

US3772187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:44:02
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
User entered '122'	(b) (4) Emily Crews (b) (4) (b) (4)	02 Nov 2020 23:28:46

US3772187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:22
User entered 'mmHg'	System	02 Nov 2020 23:28:46

US3772187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:44:02
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
User entered '64'	(b) (4) Emily Crews (b) (4) (b) (4)	02 Nov 2020 23:28:46

US3772187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:22
User entered 'mmHg'	System	02 Nov 2020 23:28:46

US3772187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:22

US3772187

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:22

US3772187

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:42:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:44:08
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	02 Nov 2020 23:28:50

US3772187

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:42:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:44:08
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	02 Nov 2020 23:28:50

US3772187

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:42:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:44:13
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
User closed query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 02NOV2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 10:05:00
Query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 02NOV2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate.' answered with 'scanned into PPD portal. Stored onsite' (Site from DM).	Emily Crews (b) (4)	13 Nov 2020 16:29:13
User opened query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 02NOV2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 16:43:06
User entered 'Yes (Y)'	Emily Crews (b) (4)	02 Nov 2020 23:29:00

US3772187

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:42:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:44:13
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
User entered '02 Nov 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	02 Nov 2020 23:29:00

US3772187

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:42:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:44:13
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
User entered '10:32'	(b) (4) Emily Crews (b) (4) (b) (4)	02 Nov 2020 23:29:00

US3772187

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:42:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User entered '02 Nov 2020 10:32'	System	02 Nov 2020 23:29:00

US3772187

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:44:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:50:21
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	02 Nov 2020 23:29:06

US3772187

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User entered '1'	System	02 Nov 2020 23:29:06

US3772187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered 'Day 64'	System	31 Aug 2020 18:00:07

US3772187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Have you had 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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-11-03T16:41:13', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '070830b8-2bb4-4f4a-a8ff-7bcb881612d2'	System	04 Nov 2020 00:41:27
User entered 'No (N)'	System	04 Nov 2020 00:41:27

US3772187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you been exposed to someone with known SARS-CoV-2 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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-11-03T16:41:18', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '070830b8-2bb4-4f4a-a8ff-7bcb881612d2'	System	04 Nov 2020 00:41:27
User entered 'No (N)'	System	04 Nov 2020 00:41:27

US3772187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-11-03T16:41:22', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '070830b8-2bb4-4f4a-a8ff-7bcb881612d2'	System	04 Nov 2020 00:41:27
User entered '03 Nov 2020 16:41:22'	System	04 Nov 2020 00:41:27

US3772187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered '31 Oct 2020 00:01'	System	31 Aug 2020 18:00:07

US3772187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered '04 Nov 2020 23:59'	System	31 Aug 2020 18:00:07

US3772187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered 'Day 71'	System	31 Aug 2020 18:00:07

US3772187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Have you had 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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-11-07T00:03:17', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '21a60610-3161-4174-9ffb-a687b19cce07'	System	07 Nov 2020 08:03:22
User entered 'No (N)'	System	07 Nov 2020 08:03:22

US3772187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you been exposed to someone with known SARS-CoV-2 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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-11-07T00:01:33', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '21a60610-3161-4174-9ffb-a687b19cce07'	System	07 Nov 2020 08:03:22
User entered 'No (N)'	System	07 Nov 2020 08:03:22

US3772187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-11-07T00:03:19', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '21a60610-3161-4174-9ffb-a687b19cce07'	System	07 Nov 2020 08:03:22
User entered '07 Nov 2020 00:03:19'	System	07 Nov 2020 08:03:22

US3772187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered '07 Nov 2020 00:01'	System	31 Aug 2020 18:00:07

US3772187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered '11 Nov 2020 23:59'	System	31 Aug 2020 18:00:07

US3772187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered 'Day 78'	System	31 Aug 2020 18:00:07

US3772187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you had 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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-11-14T00:08:59', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'f7aeefb-8981-4435-9288-0b22600c8707'	System	14 Nov 2020 08:09:08
User entered 'No (N)'	System	14 Nov 2020 08:09:08

US3772187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you been exposed to someone with known SARS-CoV-2 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 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-11-14T00:09:02', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'f7aeeafb-8981-4435-9288-0b22600c8707'	System	14 Nov 2020 08:09:08
User entered 'No (N)'	System	14 Nov 2020 08:09:08

US3772187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-11-14T00:09:04', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'f7aceafb-8981-4435-9288-0b22600c8707'	System	14 Nov 2020 08:09:08
User entered '14 Nov 2020 00:09:04'	System	14 Nov 2020 08:09:08

US3772187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered '14 Nov 2020 00:01'	System	31 Aug 2020 18:00:07

US3772187

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:25:55
Data entry locked.	System	31 Aug 2020 18:00:07
User entered '18 Nov 2020 23:59'	System	31 Aug 2020 18:00:07

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Have you had 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 (813e4d637d445d0b)', Time: '2020-11-26T10:43:53', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '420e6dec-bc70-40d5-a46b-2d4eba9b6ca7'	System	26 Nov 2020 18:44:01
User entered 'No (N)'	System	26 Nov 2020 18:44:01

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you been exposed to someone with known SARS-CoV-2 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 (813e4d637d445d0b)', Time: '2020-11-26T10:43:55', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '420e6dec-bc70-40d5-a46b-2d4eba9b6ca7'	System	26 Nov 2020 18:44:01
User entered 'No (N)'	System	26 Nov 2020 18:44:01

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-11-26T10:43:58', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '420e6dec-bc70-40d5-a46b-2d4eba9b6ca7'	System	26 Nov 2020 18:44:01
User entered '26 Nov 2020 10:43:58'	System	26 Nov 2020 18:44:01

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Have you had 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 (813e4d637d445d0b)', Time: '2020-12-02T00:37:06', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '0dec3dd9-5072-47ed-a5b9-4176da5b7489'	System	02 Dec 2020 08:38:09
User entered 'Yes (Y)'	System	02 Dec 2020 08:38:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you been exposed to someone with known SARS-CoV-2 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 (813e4d637d445d0b)', Time: '2020-12-02T00:37:16', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '0dec3dd9-5072-47ed-a5b9-4176da5b7489'	System	02 Dec 2020 08:38:09
User entered 'No (N)'	System	02 Dec 2020 08:38:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-12-02T00:37:20', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '0dec3dd9-5072-47ed-a5b9-4176da5b7489'	System	02 Dec 2020 08:38:09
User entered 'Yes (Y)'	System	02 Dec 2020 08:38:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-12-02T00:37:46', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '0dec3dd9-5072-47ed-a5b9-4176da5b7489'	System	02 Dec 2020 08:38:09
User entered '1'	System	02 Dec 2020 08:38:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-12-02T00:37:46', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '0dec3dd9-5072-47ed-a5b9-4176da5b7489'	System	02 Dec 2020 08:38:09
User entered '1'	System	02 Dec 2020 08:38:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-12-02T00:37:46', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '0dec3dd9-5072-47ed-a5b9-4176da5b7489'	System	02 Dec 2020 08:38:09
User entered '0'	System	02 Dec 2020 08:38:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-12-02T00:37:46', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '0dec3dd9-5072-47ed-a5b9-4176da5b7489'	System	02 Dec 2020 08:38:09
User entered '0'	System	02 Dec 2020 08:38:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-12-02T00:37:46', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '0dec3dd9-5072-47ed-a5b9-4176da5b7489'	System	02 Dec 2020 08:38:09
User entered '0'	System	02 Dec 2020 08:38:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-12-02T00:37:46', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '0dec3dd9-5072-47ed-a5b9-4176da5b7489'	System	02 Dec 2020 08:38:09
User entered '1'	System	02 Dec 2020 08:38:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-12-02T00:37:46', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '0dec3dd9-5072-47ed-a5b9-4176da5b7489'	System	02 Dec 2020 08:38:09
User entered '1'	System	02 Dec 2020 08:38:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-12-02T00:37:46', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '0dec3dd9-5072-47ed-a5b9-4176da5b7489'	System	02 Dec 2020 08:38:09
User entered '1'	System	02 Dec 2020 08:38:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-12-02T00:37:46', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '0dec3dd9-5072-47ed-a5b9-4176da5b7489'	System	02 Dec 2020 08:38:09
User entered '1'	System	02 Dec 2020 08:38:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-12-02T00:37:46', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '0dec3dd9-5072-47ed-a5b9-4176da5b7489'	System	02 Dec 2020 08:38:09
User entered '0'	System	02 Dec 2020 08:38:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-12-02T00:37:46', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '0dec3dd9-5072-47ed-a5b9-4176da5b7489'	System	02 Dec 2020 08:38:09
User entered '0'	System	02 Dec 2020 08:38:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-12-02T00:37:46', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '0dec3dd9-5072-47ed-a5b9-4176da5b7489'	System	02 Dec 2020 08:38:09
User entered '0'	System	02 Dec 2020 08:38:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-12-02T00:37:46', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '0dec3dd9-5072-47ed-a5b9-4176da5b7489'	System	02 Dec 2020 08:38:09
User entered '0'	System	02 Dec 2020 08:38:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-12-02T00:37:46', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '0dec3dd9-5072-47ed-a5b9-4176da5b7489'	System	02 Dec 2020 08:38:09
User entered '0'	System	02 Dec 2020 08:38:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-12-02T00:37:46', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '0dec3dd9-5072-47ed-a5b9-4176da5b7489'	System	02 Dec 2020 08:38:09
User entered '1'	System	02 Dec 2020 08:38:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-12-02T00:37:46', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '0dec3dd9-5072-47ed-a5b9-4176da5b7489'	System	02 Dec 2020 08:38:09
User entered '1'	System	02 Dec 2020 08:38:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-12-02T00:37:46', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '0dec3dd9-5072-47ed-a5b9-4176da5b7489'	System	02 Dec 2020 08:38:09
User entered '0'	System	02 Dec 2020 08:38:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-12-02T00:37:51', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '0dec3dd9-5072-47ed-a5b9-4176da5b7489'	System	02 Dec 2020 08:38:09
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Dec 2020 08:38:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-12-02T00:37:57', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '0dec3dd9-5072-47ed-a5b9-4176da5b7489'	System	02 Dec 2020 08:38:09
User entered 'No (N)'	System	02 Dec 2020 08:38:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-12-02T00:38:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '0dec3dd9-5072-47ed-a5b9-4176da5b7489'	System	02 Dec 2020 08:38:09
User entered '02 Dec 2020 00:38:00'	System	02 Dec 2020 08:38:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Have you had 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 (813e4d637d445d0b)', Time: '2020-12-10T14:33:28', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'a248e621-ca77-4fee-a8ff-b4fbc0b8354c'	System	10 Dec 2020 22:33:41
User entered 'No (N)'	System	10 Dec 2020 22:33:41

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you been exposed to someone with known SARS-CoV-2 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 (813e4d637d445d0b)', Time: '2020-12-10T14:33:32', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'a248e621-ca77-4fee-a8ff-b4fbc0b8354c'	System	10 Dec 2020 22:33:41
User entered 'No (N)'	System	10 Dec 2020 22:33:41

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-12-10T14:33:35', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'a248e621-ca77-4fee-a8ff-b4fbc0b8354c'	System	10 Dec 2020 22:33:41
User entered '10 Dec 2020 14:33:35'	System	10 Dec 2020 22:33:41

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Have you had 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 (813e4d637d445d0b)', Time: '2020-12-18T02:14:31', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '0e8c05a1-6ceb-4a4c-b5c9-110cece58cc4'	System	18 Dec 2020 10:14:47
User entered 'No (N)'	System	18 Dec 2020 10:14:47

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you been exposed to someone with known SARS-CoV-2 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 (813e4d637d445d0b)', Time: '2020-12-18T02:14:42', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '0e8c05a1-6ceb-4a4c-b5c9-110cece58cc4'	System	18 Dec 2020 10:14:47
User entered 'No (N)'	System	18 Dec 2020 10:14:47

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-12-18T02:14:44', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '0e8c05a1-6ceb-4a4c-b5c9-110cece58cc4'	System	18 Dec 2020 10:14:47
User entered '18 Dec 2020 02:14:44'	System	18 Dec 2020 10:14:47

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you had 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 (813e4d637d445d0b)', Time: '2020-12-24T14:01:47', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '6d757fa1-c85c-4b20-b286-ec5d91300b8d'	System	24 Dec 2020 22:01:55
User entered 'No (N)'	System	24 Dec 2020 22:01:55

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you been exposed to someone with known SARS-CoV-2 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 (813e4d637d445d0b)', Time: '2020-12-24T14:01:49', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '6d757fa1-c85c-4b20-b286-ec5d91300b8d'	System	24 Dec 2020 22:01:55
User entered 'No (N)'	System	24 Dec 2020 22:01:55

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-12-24T14:01:52', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '6d757fa1-c85c-4b20-b286-ec5d91300b8d'	System	24 Dec 2020 22:01:55
User entered '24 Dec 2020 14:01:52'	System	24 Dec 2020 22:01:55

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Have you had 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 (813e4d637d445d0b)', Time: '2020-12-31T11:54:11', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '988e2ef5-364b-43e7-8eb1-c03642384518'	System	31 Dec 2020 19:54:25
User entered 'No (N)'	System	31 Dec 2020 19:54:25

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you been exposed to someone with known SARS-CoV-2 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 (813e4d637d445d0b)', Time: '2020-12-31T11:54:17', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '988e2ef5-364b-43e7-8eb1-c03642384518'	System	31 Dec 2020 19:54:25
User entered 'No (N)'	System	31 Dec 2020 19:54:25

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2020-12-31T11:54:20', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '988e2ef5-364b-43e7-8eb1-c03642384518'	System	31 Dec 2020 19:54:25
User entered '31 Dec 2020 11:54:20'	System	31 Dec 2020 19:54:25

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you had 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 (813e4d637d445d0b)', Time: '2021-01-06T15:36:52', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'a2aceeb0-e6e3-442d-b325-8f6f4cc4c6a6'	System	06 Jan 2021 23:37:13
User entered 'No (N)'	System	06 Jan 2021 23:37:13

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you been exposed to someone with known SARS-CoV-2 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 (813e4d637d445d0b)', Time: '2021-01-06T15:37:02', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'a2aceeb0-e6e3-442d-b325-8f6f4cc4c6a6'	System	06 Jan 2021 23:37:13
User entered 'No (N)'	System	06 Jan 2021 23:37:13

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2021-01-06T15:37:09', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'a2aceeb0-e6e3-442d-b325-8f6f4cc4c6a6'	System	06 Jan 2021 23:37:13
User entered '06 Jan 2021 15:37:09'	System	06 Jan 2021 23:37:13

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Have you had 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 (813e4d637d445d0b)', Time: '2021-01-13T01:51:15', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '37957d52-3ea5-4599-9d9c-df9527d2e55d'	System	13 Jan 2021 09:51:34
User entered 'No (N)'	System	13 Jan 2021 09:51:34

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you been exposed to someone with known SARS-CoV-2 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 (813e4d637d445d0b)', Time: '2021-01-13T01:51:26', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '37957d52-3ea5-4599-9d9c-df9527d2e55d'	System	13 Jan 2021 09:51:34
User entered 'No (N)'	System	13 Jan 2021 09:51:34

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2021-01-13T01:51:31', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '37957d52-3ea5-4599-9d9c-df9527d2e55d'	System	13 Jan 2021 09:51:34
User entered '13 Jan 2021 01:51:31'	System	13 Jan 2021 09:51:34

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Have you had 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 (813e4d637d445d0b)', Time: '2021-01-20T20:26:35', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '37abd7e5-dee5-4b90-804e-7c7c6049057b'	System	21 Jan 2021 04:26:47
User entered 'No (N)'	System	21 Jan 2021 04:26:47

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you been exposed to someone with known SARS-CoV-2 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 (813e4d637d445d0b)', Time: '2021-01-20T20:26:41', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '37abd7e5-dee5-4b90-804e-7c7c6049057b'	System	21 Jan 2021 04:26:47
User entered 'No (N)'	System	21 Jan 2021 04:26:47

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2021-01-20T20:26:43', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '37abd7e5-dee5-4b90-804e-7c7c6049057b'	System	21 Jan 2021 04:26:47
User entered '20 Jan 2021 20:26:43'	System	21 Jan 2021 04:26:47

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Have you had 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 (813e4d637d445d0b)', Time: '2021-01-27T16:09:03', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '3cdae15f-24fe-414e-a173-faa9be2be2f4'	System	28 Jan 2021 00:10:44
User entered 'No (N)'	System	28 Jan 2021 00:10:44

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you been exposed to someone with known SARS-CoV-2 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 (813e4d637d445d0b)', Time: '2021-01-27T16:09:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '3cdae15f-24fe-414e-a173-faa9be2be2f4'	System	28 Jan 2021 00:10:44
User entered 'Yes (Y)'	System	28 Jan 2021 00:10:44

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2021-01-27T16:09:14', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '3cdae15f-24fe-414e-a173-faa9be2be2f4'	System	28 Jan 2021 00:10:44
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Jan 2021 00:10:44

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2021-01-27T16:10:32', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '3cdae15f-24fe-414e-a173-faa9be2be2f4' User entered '27 Jan 2021 16:10:32'	System	28 Jan 2021 00:10:44
	System	28 Jan 2021 00:10:44

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Have you had 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 (813e4d637d445d0b)', Time: '2021-02-03T00:13:36', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'd269a0fc-4e85-41c2-bc28-57101a2f8157'	System	03 Feb 2021 08:13:50
User entered 'No (N)'	System	03 Feb 2021 08:13:50

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you been exposed to someone with known SARS-CoV-2 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 (813e4d637d445d0b)', Time: '2021-02-03T00:13:44', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'd269a0fc-4e85-41c2-bc28-57101a2f8157'	System	03 Feb 2021 08:13:50
User entered 'No (N)'	System	03 Feb 2021 08:13:50

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2021-02-03T00:13:47', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'd269a0fc-4e85-41c2-bc28-57101a2f8157'	System	03 Feb 2021 08:13:50
User entered '03 Feb 2021 00:13:47'	System	03 Feb 2021 08:13:50

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Have you had 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 (813e4d637d445d0b)', Time: '2021-02-14T08:39:43', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '9dbccdcd-da48-45ba-b065-e98abdb9da03'	System	14 Feb 2021 16:39:57
User entered 'No (N)'	System	14 Feb 2021 16:39:57

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you been exposed to someone with known SARS-CoV-2 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 (813e4d637d445d0b)', Time: '2021-02-14T08:39:46', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '9dbccdcd-da48-45ba-b065-e98abdb9da03'	System	14 Feb 2021 16:39:57
User entered 'No (N)'	System	14 Feb 2021 16:39:57

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2021-02-14T08:39:54', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '9dbccdcd-da48-45ba-b065-e98abdb9da03'	System	14 Feb 2021 16:39:57
User entered '14 Feb 2021 08:39:54'	System	14 Feb 2021 16:39:57

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Have you had 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 (813e4d637d445d0b)', Time: '2021-02-17T00:08:50', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '544148fa-e14d-4426-be3a-26d6ea83e708'	System	17 Feb 2021 08:09:06
User entered 'No (N)'	System	17 Feb 2021 08:09:06

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you been exposed to someone with known SARS-CoV-2 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 (813e4d637d445d0b)', Time: '2021-02-17T00:08:57', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '544148fa-e14d-4426-be3a-26d6ea83e708'	System	17 Feb 2021 08:09:06
User entered 'No (N)'	System	17 Feb 2021 08:09:06

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2021-02-17T00:09:01', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '544148fa-e14d-4426-be3a-26d6ea83e708'	System	17 Feb 2021 08:09:06
User entered '17 Feb 2021 00:09:01'	System	17 Feb 2021 08:09:06

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Have you had 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 (813e4d637d445d0b)', Time: '2021-02-24T09:40:42-08:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '207b86b5-f0dd-4ad7-888a-41df636c457c'	System	24 Feb 2021 17:40:54
User entered 'No (N)'	System	24 Feb 2021 17:40:54

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you been exposed to someone with known SARS-CoV-2 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 (813e4d637d445d0b)', Time: '2021-02-24T09:40:48-08:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '207b86b5-f0dd-4ad7-888a-41df636c457c'	System	24 Feb 2021 17:40:54
User entered 'No (N)'	System	24 Feb 2021 17:40:54

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2021-02-24T09:40:50-08:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '207b86b5-f0dd-4ad7-888a-41df636c457c' User entered '24 Feb 2021 09:40:50'	System	24 Feb 2021 17:40:54

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Have you had 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 (813e4d637d445d0b)', Time: '2021-03-03T11:22:28-08:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '10facafa-8b72-4d09-a2d6-f6f130630561'	System	03 Mar 2021 19:22:41
User entered 'No (N)'	System	03 Mar 2021 19:22:41

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you been exposed to someone with known SARS-CoV-2 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 (813e4d637d445d0b)', Time: '2021-03-03T11:22:34-08:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '10facafa-8b72-4d09-a2d6-f6f130630561'	System	03 Mar 2021 19:22:41
User entered 'No (N)'	System	03 Mar 2021 19:22:41

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2021-03-03T11:22:37-08:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '10facafa-8b72-4d09-a2d6-f6f130630561' User entered '03 Mar 2021 11:22:37'	System	03 Mar 2021 19:22:41
	System	03 Mar 2021 19:22:41

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Have you had 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 (813e4d637d445d0b)', Time: '2021-03-12T14:17:31-08:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '979deaa4-7f86-4d0f-ac1f-85965f58d897'	System	12 Mar 2021 22:17:40
User entered 'No (N)'	System	12 Mar 2021 22:17:40

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you been exposed to someone with known SARS-CoV-2 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 (813e4d637d445d0b)', Time: '2021-03-12T14:17:34-08:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '979deaa4-7f86-4d0f-ac1f-85965f58d897'	System	12 Mar 2021 22:17:40
User entered 'No (N)'	System	12 Mar 2021 22:17:40

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2021-03-12T14:17:37-08:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '979deaa4-7f86-4d0f-ac1f-85965f58d897'	System	12 Mar 2021 22:17:40
User entered '12 Mar 2021 14:17:37'	System	12 Mar 2021 22:17:40

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you had 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 (813e4d637d445d0b)', Time: '2021-03-17T10:47:23-07:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '592f5de7-a337-4991-a01a-61d28a5fd18c'	System	17 Mar 2021 17:47:37
User entered 'No (N)'	System	17 Mar 2021 17:47:37

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you been exposed to someone with known SARS-CoV-2 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 (813e4d637d445d0b)', Time: '2021-03-17T10:47:30-07:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '592f5de7-a337-4991-a01a-61d28a5fd18c'	System	17 Mar 2021 17:47:37
User entered 'No (N)'	System	17 Mar 2021 17:47:37

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2021-03-17T10:47:32-07:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '592f5de7-a337-4991-a01a-61d28a5fd18c' User entered '17 Mar 2021 10:47:32'	System	17 Mar 2021 17:47:37
	System	17 Mar 2021 17:47:37

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Have you had 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 (813e4d637d445d0b)', Time: '2021-03-24T07:13:36-07:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '0f1b66e2-0f4b-46a9-8ab2-16237786dbc9'	System	24 Mar 2021 14:13:50
User entered 'No (N)'	System	24 Mar 2021 14:13:50

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you been exposed to someone with known SARS-CoV-2 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 (813e4d637d445d0b)', Time: '2021-03-24T07:13:43-07:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '0f1b66e2-0f4b-46a9-8ab2-16237786dbc9'	System	24 Mar 2021 14:13:50
User entered 'No (N)'	System	24 Mar 2021 14:13:50

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2021-03-24T07:13:46-07:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '0f1b66e2-0f4b-46a9-8ab2-16237786dbc9' User entered '24 Mar 2021 07:13:46'	System	24 Mar 2021 14:13:50
	System	24 Mar 2021 14:13:50

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Have you had 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 (813e4d637d445d0b)', Time: '2021-03-31T09:47:56-07:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '5b287eb8-d947-408a-b4a2-51924b219a1b'	System	31 Mar 2021 16:48:08
User entered 'No (N)'	System	31 Mar 2021 16:48:08

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you been exposed to someone with known SARS-CoV-2 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 (813e4d637d445d0b)', Time: '2021-03-31T09:47:59-07:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '5b287eb8-d947-408a-b4a2-51924b219a1b'	System	31 Mar 2021 16:48:08
User entered 'No (N)'	System	31 Mar 2021 16:48:08

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2021-03-31T09:48:01-07:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '5b287eb8-d947-408a-b4a2-51924b219a1b'	System	31 Mar 2021 16:48:08
User entered '31 Mar 2021 09:48:01'	System	31 Mar 2021 16:48:08

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Have you had 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 (813e4d637d445d0b)', Time: '2021-04-07T00:18:09-07:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'f6c76c60-5297-46f8-9504-9e70e74740d2'	System	07 Apr 2021 07:18:18
User entered 'No (N)'	System	07 Apr 2021 07:18:18

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you been exposed to someone with known SARS-CoV-2 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 (813e4d637d445d0b)', Time: '2021-04-07T00:18:12-07:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'f6c76c60-5297-46f8-9504-9e70e74740d2'	System	07 Apr 2021 07:18:18
User entered 'No (N)'	System	07 Apr 2021 07:18:18

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2021-04-07T00:18:15-07:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'f6c76c60-5297-46f8-9504-9e70e74740d2'	System	07 Apr 2021 07:18:18
User entered '07 Apr 2021 00:18:15'	System	07 Apr 2021 07:18:18

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Have you had 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 (813e4d637d445d0b)', Time: '2021-04-15T07:07:52-07:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'd8508a8d-c60f-43f3-8891-88ec4ce1f8d4'	System	15 Apr 2021 14:08:18
User entered 'No (N)'	System	15 Apr 2021 14:08:18

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you been exposed to someone with known SARS-CoV-2 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 (813e4d637d445d0b)', Time: '2021-04-15T07:07:55-07:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'd8508a8d-c60f-43f3-8891-88ec4ce1f8d4'	System	15 Apr 2021 14:08:18
User entered 'No (N)'	System	15 Apr 2021 14:08:18

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2021-04-15T07:07:58-07:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'd8508a8d-c60f-43f3-8891-88ec4ce1f8d4'	System	15 Apr 2021 14:08:18
User entered '15 Apr 2021 07:07:58'	System	15 Apr 2021 14:08:18

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Have you had 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 (813e4d637d445d0b)', Time: '2021-04-21T00:05:04-07:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '26c473d1-b5fe-4e29-9f0d-0dc4e11f50d1'	System	21 Apr 2021 07:05:13
User entered 'No (N)'	System	21 Apr 2021 07:05:13

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you been exposed to someone with known SARS-CoV-2 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 (813e4d637d445d0b)', Time: '2021-04-21T00:05:07-07:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '26c473d1-b5fe-4e29-9f0d-0dc4e11f50d1'	System	21 Apr 2021 07:05:13
User entered 'No (N)'	System	21 Apr 2021 07:05:13

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2021-04-21T00:05:09-07:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: '26c473d1-b5fe-4e29-9f0d-0dc4e11f50d1'	System	21 Apr 2021 07:05:13
User entered '21 Apr 2021 00:05:09'	System	21 Apr 2021 07:05:13

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Have you had 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 (813e4d637d445d0b)', Time: '2021-04-29T09:03:16-07:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'a9fd88bf-cb67-4ffb-a0ad-0eb3f057db43'	System	29 Apr 2021 16:08:53
User entered 'No (N)'	System	29 Apr 2021 16:08:53

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

Have you been exposed to someone with known SARS-CoV-2 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 (813e4d637d445d0b)', Time: '2021-04-29T09:03:35-07:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'a9fd88bf-cb67-4ffb-a0ad-0eb3f057db43'	System	29 Apr 2021 16:08:53
User entered 'No (N)'	System	29 Apr 2021 16:08:53

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2021-04-29T09:03:38-07:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'a9fd88bf-cb67-4ffb-a0ad-0eb3f057db43'	System	29 Apr 2021 16:08:53
User entered '29 Apr 2021 09:03:38'	System	29 Apr 2021 16:08:53

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '26 Oct 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '30 Oct 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '02 Nov 2022 00:01'	System	19 Nov 2020 21:02:09

US3772187

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:42:05

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:02:09
Amendment Manager: User entered '06 Nov 2022 23:59'	System	19 Nov 2020 21:02:09

US3772187

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:42:05

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)	29 Apr 2021 19:44:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2021-03-03T11:22:50-08:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'e0332572-af89-4148-8c8c-984501e7ec15'	System	03 Mar 2021 19:22:58
User entered 'No (N)'	System	03 Mar 2021 19:22:58

US3772187

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:42:05

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:44:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (813e4d637d445d0b)', Time: '2021-03-03T11:22:53-08:00', User OID: 'PatientReportedOutcome (US3772187)', ODM File OID: 'e0332572-af89-4148-8c8c-984501e7ec15'	System	03 Mar 2021 19:22:58
User entered '03 Mar 2021 11:22:53'	System	03 Mar 2021 19:22:58

US3772187

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:15:17
User entered 'Yes (Y)'	Sarah Sandberg (b) (4) (b) (4)	24 Nov 2020 23:36:41

US3772187

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:15:17
User entered '24 Nov 2020'	Sarah Sandberg (b) (4) (b) (4)	24 Nov 2020 23:36:41

US3772187

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:15:17
User entered 'Contact Made (CONTACT MADE)'	Sarah Sandberg (b) (4) (b) (4)	24 Nov 2020 23:36:41

US3772187

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:15:17
User entered empty.	Sarah Sandberg (b) (4) (b) (4)	24 Nov 2020 23:36:41

US3772187

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:06:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:15:21
User entered 'Yes (Y)'	Sarah Sandberg (b) (4) (b) (4)	24 Nov 2020 23:36:44

US3772187

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:28:17
User entered '1'	System	24 Nov 2020 23:36:44

US3772187

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:55:55
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:00:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:16:28
User entered 'Yes (Y)'	Marisol Corrales (b) (4) (b) (4)	29 Dec 2020 00:03:14

US3772187

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:55:55
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:00:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:16:28
User entered '28 Dec 2020'	Marisol Corrales (b) (4) (b) (4)	29 Dec 2020 00:03:14

US3772187

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:55:55
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:00:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:16:28
User entered 'Contact Made (CONTACT MADE)'	Marisol Corrales (b) (4) (b) (4)	29 Dec 2020 00:03:14

US3772187

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:55:55
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:00:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:16:28
User entered empty.	Marisol Corrales (b) (4) (b) (4)	29 Dec 2020 00:03:14

US3772187

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:55:55
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:16:20
User entered 'Yes (Y)'	Marisol Corrales (b) (4) (b) (4)	29 Dec 2020 00:03:20

US3772187

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:55:55
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User entered '1'	System	29 Dec 2020 00:03:20

US3772187

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:55:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:44:42
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:00:56
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	19 Feb 2021 20:08:16

US3772187

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:55:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:44:42
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:00:56
User entered '27 Jan 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	19 Feb 2021 20:08:16

US3772187

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:55:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:44:42
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:00:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Emily Crews (b) (4) (b) (4)	19 Feb 2021 20:08:16

US3772187

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:55:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:44:42
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:00:56
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	19 Feb 2021 20:08:16

US3772187

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:55:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:44:47
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	19 Feb 2021 20:08:26

US3772187

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:55:55
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User entered '1'	System	19 Feb 2021 20:08:26

US3772187

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:55:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:44:54
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:00:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 16:29:14

US3772187

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:55:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:44:54
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:00:56
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 16:29:14

US3772187

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:55:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:44:54
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:00:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 16:29:14

US3772187

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:55:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:44:54
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:00:56
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 16:29:14

US3772187

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:55:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:44:59
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 16:29:20

US3772187

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:55:55
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User entered '1'	System	26 Feb 2021 16:29:20

US3772187

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:01
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:45:04
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'Yes (Y)'	(b) (4) Marisol Corrales (b) (4)	22 Mar 2021 17:47:06
	(b) (4)	

US3772187

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:01
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:45:04
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered '22 Mar 2021'	(b) (4) Marisol Corrales (b) (4) (b) (4)	22 Mar 2021 17:47:06

US3772187

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

[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 09:54:01
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:45:04
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'Clinic (Clinic)'	(b) (4) Marisol Corrales (b) (4) (b) (4)	22 Mar 2021 17:47:06

US3772187

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:01
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User entered 'VISIT4'	System	22 Mar 2021 17:47:06

US3772187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:01
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:45:11
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:37:25
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:48:01

US3772187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:01
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:45:11
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:37:25
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:48:01

US3772187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:01
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:45:11
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:37:25
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:48:01

US3772187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:01
User entered empty.	System	01 Apr 2021 21:48:01

US3772187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:01
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:45:11
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4) (b) (4)	02 Apr 2021 02:37:25
User entered empty.	Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:48:01

US3772187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:01
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:45:11
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4) (b) (4)	02 Apr 2021 02:37:25
User entered empty.	Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:48:01

US3772187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:01
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:45:11
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:37:25
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:48:01

US3772187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:01
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:45:11
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:37:25
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:48:01

US3772187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:01
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User entered empty.	System	01 Apr 2021 21:48:01

US3772187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:01
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:45:11
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4) (b) (4)	02 Apr 2021 02:37:25
User entered empty.	Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:48:01

US3772187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:01
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User entered empty.	System	01 Apr 2021 21:48:01

US3772187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:01
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:45:11
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:37:25
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:48:01

US3772187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:01
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User entered empty.	System	01 Apr 2021 21:48:01

US3772187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:01
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:45:11
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:37:25
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:48:01

US3772187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:01
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User entered empty.	System	01 Apr 2021 21:48:01

US3772187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:01
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02

US3772187

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:01
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02

US3772187

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:42:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:01
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:45:16
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'No (N)'	(b) (4) Marisol Corrales (b) (4) (b) (4)	22 Mar 2021 17:47:11

US3772187

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:42:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:01
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:45:16
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered empty.	(b) (4) Marisol Corrales (b) (4) (b) (4)	22 Mar 2021 17:47:11

US3772187

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:42:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:01
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:45:21
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'Yes (Y)'	(b) (4) Marisol Corrales (b) (4)	22 Mar 2021 17:47:23
	(b) (4)	

US3772187

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:42:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:01
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:45:21
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered '22 Mar 2021'	(b) (4) Marisol Corrales (b) (4) (b) (4)	22 Mar 2021 17:47:23

US3772187

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:42:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:01
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:45:21
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered '10:32'	(b) (4) Marisol Corrales (b) (4) (b) (4)	22 Mar 2021 17:47:23

US3772187

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:42:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:01
User entered '22 Mar 2021 10:32'	System	22 Mar 2021 17:47:23

US3772187

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:01
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:45:26
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'Yes (Y)'	(b) (4) Marisol Corrales (b) (4)	22 Mar 2021 17:47:27
	(b) (4)	

US3772187

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:54:01
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:53:02
User entered '1'	System	22 Mar 2021 17:47:27

US3772187

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	03 May 2021 19:24:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:27:34

US3772187

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	03 May 2021 19:24:58
User entered '26 Apr 2021'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:27:34

US3772187

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	03 May 2021 19:24:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:27:34

US3772187

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	03 May 2021 19:24:58
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:27:34

US3772187

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	03 May 2021 19:24:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:27:43

US3772187

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Apr 2021 19:27:43

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:42:05

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:49
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:29:46
User entered '01 Dec 2020'	Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 20:57:58

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:42:05

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:49
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:29:46
User entered '12:21'	Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 20:57:58

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:42:05

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:49
User entered '01 Dec 2020 12:21'	System	03 Dec 2020 20:57:58

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:42:05

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:49
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:29:46
User entered 'Safety Call (Safety Call)'	Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 20:57:58

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:42:05

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:49
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:29:46
User entered 'Yes (Y)'	Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 20:57:58

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:42:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Day 1 (Day 1)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:00:31

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:42:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '30 Nov 2020'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:00:31

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:42:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:00:31

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:42:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered missing code ND - Not Done.	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:00:31

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:42:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
User entered '%'	System	03 Dec 2020 21:00:31

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:42:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered missing code ND - Not Done.	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:00:31

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:42:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:00:31

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:42:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:00:31

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:42:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:00:31

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:42:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:00:31

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:42:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:00:31

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:42:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:00:31

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:42:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:00:31

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:42:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Mild (Mild)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:00:31

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:42:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:00:31

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:42:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:00:31

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:42:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Mild (Mild)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:00:31

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:42:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:00:31

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:42:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:00:31

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:42:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Mild (Mild)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:00:31

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:42:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:00:31

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:42:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:00:31

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:42:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Day 2 (Day 2)'	(b) (4) Sarah Sandberg (b) (4)	03 Dec 2020 21:01:44

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:42:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '01 Dec 2020'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:01:44

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:42:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:01:44

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:42:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered missing code ND - Not Done.	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:01:44

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:42:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
User entered '%'	System	03 Dec 2020 21:01:44

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:42:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered missing code ND - Not Done.	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:01:44

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:42:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:01:44

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:42:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:01:44

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:42:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:01:44

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:42:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:01:44

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:42:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:01:44

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:42:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:01:44

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:42:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:01:44

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:42:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Mild (Mild)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:01:44

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:42:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:01:44

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:42:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:01:44

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:42:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Mild (Mild)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:01:44

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:42:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:01:44

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:42:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:01:44

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:42:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:01:44

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:42:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:01:44

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:42:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:01:44

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:42:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Day 3 (Day 3)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:03:37

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:42:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '02 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Sarah Sandberg (b) (4)	05 Dec 2020 18:58:09
User entered '02 Nov 2020'	(b) (4)	
	Sarah Sandberg (b) (4)	03 Dec 2020 21:03:37
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:42:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:03:37

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:42:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '98'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:03:37

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:42:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
User entered '%'	System	03 Dec 2020 21:03:37

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:42:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '37.5' C	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:03:37

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:42:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:03:37

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:42:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:03:37

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:42:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:03:37

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:42:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:03:37

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:42:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:03:37

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:42:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:03:37

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:42:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:03:37

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:42:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:03:37

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:42:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:03:37

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:42:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:03:37

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:42:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:03:37

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:42:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:03:37

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:42:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:03:37

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:42:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:03:37

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:42:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:03:37

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:42:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:03:37

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:42:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Day 4 (Day 4)'	(b) (4) Matthew Pohlmeier (b) (4)	04 Dec 2020 00:09:36

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:42:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '03 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Sarah Sandberg (b) (4)	05 Dec 2020 18:58:09
User entered '03 Nov 2020'	(b) (4)	
	Matthew Pohlmeier	04 Dec 2020 00:09:36
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:42:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '0'	(b) (4) Matthew Pohlmeier (b) (4)	04 Dec 2020 00:09:36

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:42:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '100'	(b) (4) Matthew Pohlmeier (b) (4)	04 Dec 2020 00:09:36

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:42:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
User entered '%'	System	04 Dec 2020 00:09:36

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:42:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '98.9' F	(b) (4) Matthew Pohlmeier (b) (4)	04 Dec 2020 00:09:36

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:42:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	04 Dec 2020 00:09:36

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:42:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	04 Dec 2020 00:09:36

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:42:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	04 Dec 2020 00:09:36

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:42:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	04 Dec 2020 00:09:36

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:42:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	04 Dec 2020 00:09:36

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:42:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Mild (Mild)'	(b) (4) Matthew Pohlmeier (b) (4)	04 Dec 2020 00:09:36

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:42:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Mild (Mild)'	(b) (4) Matthew Pohlmeier (b) (4)	04 Dec 2020 00:09:36

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:42:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	04 Dec 2020 00:09:36

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:42:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	04 Dec 2020 00:09:36

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:42:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	04 Dec 2020 00:09:36

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:42:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	04 Dec 2020 00:09:36

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:42:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	04 Dec 2020 00:09:36

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:42:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	04 Dec 2020 00:09:36

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:42:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	04 Dec 2020 00:09:36

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:42:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	04 Dec 2020 00:09:36

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:42:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	04 Dec 2020 00:09:36

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:42:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Day 5 (Day 5)'	(b) (4) Sarah Sandberg (b) (4)	05 Dec 2020 18:57:06

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:42:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '04 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Sarah Sandberg (b) (4)	05 Dec 2020 18:58:09
User entered '04 Nov 2020'	(b) (4)	
	Sarah Sandberg (b) (4)	05 Dec 2020 18:57:06
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:42:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:57:06

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:42:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '100'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:57:06

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:42:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
User entered '%'	System	05 Dec 2020 18:57:06

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:42:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '97.8' F	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:57:06

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:42:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:57:06

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:42:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:57:06

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:42:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:57:06

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:42:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:57:06

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:42:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:57:06

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:42:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Mild (Mild)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:57:06

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:42:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Mild (Mild)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:57:06

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:42:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:57:06

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:42:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:57:06

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:42:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:57:06

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:42:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:57:06

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:42:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:57:06

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:42:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:57:06

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:42:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:57:06

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:42:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:57:06

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:42:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:57:06

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:42:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Day 6 (Day 6)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:58:09

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:42:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '05 Dec 2020'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:58:09

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:42:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:58:09

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:42:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '100'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:58:09

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:42:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
User entered '%'	System	05 Dec 2020 18:58:09

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:42:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '98.5' F	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:58:09

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:42:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:58:09

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:42:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:58:09

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:42:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:58:09

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:42:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:58:09

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:42:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:58:09

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:42:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Mild (Mild)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:58:09

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:42:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Mild (Mild)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:58:09

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:42:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:58:09

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:42:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:58:09

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:42:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:58:09

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:42:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:58:09

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:42:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:58:09

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:42:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:58:09

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:42:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:58:09

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:42:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:58:09

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:42:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Dec 2020 18:58:09

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:42:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Day 7 (Day 7)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	07 Dec 2020 19:53:26

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:42:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '06 Dec 2020'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	07 Dec 2020 19:53:26

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:42:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	07 Dec 2020 19:53:26

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:42:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '98'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	07 Dec 2020 19:53:26

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:42:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
User entered '%'	System	07 Dec 2020 19:53:26

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:42:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '100.6' F	(b) (4) Sarah Sandberg (b) (4) (b) (4)	07 Dec 2020 19:53:26

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:42:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	07 Dec 2020 19:53:26

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:42:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	07 Dec 2020 19:53:26

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:42:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	07 Dec 2020 19:53:26

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:42:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	07 Dec 2020 19:53:26

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:42:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	07 Dec 2020 19:53:26

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:42:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Mild (Mild)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	07 Dec 2020 19:53:26

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:42:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Mild (Mild)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	07 Dec 2020 19:53:26

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:42:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	07 Dec 2020 19:53:26

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:42:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	07 Dec 2020 19:53:26

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:42:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	07 Dec 2020 19:53:26

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:42:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	07 Dec 2020 19:53:26

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:42:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	07 Dec 2020 19:53:26

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:42:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	07 Dec 2020 19:53:26

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:42:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	07 Dec 2020 19:53:26

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:42:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	07 Dec 2020 19:53:26

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:42:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	07 Dec 2020 19:53:26

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:42:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Day 8 (Day 8)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 00:15:01

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:42:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '7 Dec 2020'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 00:15:01

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:42:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '0'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 00:15:01

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:42:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '100'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 00:15:01

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:42:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
User entered '%'	System	08 Dec 2020 00:15:01

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:42:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '100.6' F	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 00:15:01

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:42:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 00:15:01

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:42:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	08 Dec 2020 00:17:41
User entered empty.	Ruba Zanaid (b) (4)	08 Dec 2020 00:15:01
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:42:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	08 Dec 2020 00:17:41
User entered empty.	Ruba Zanaid (b) (4)	08 Dec 2020 00:15:01
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:42:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	08 Dec 2020 00:17:41
User entered empty.	Ruba Zanaid (b) (4)	08 Dec 2020 00:15:01
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:42:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	08 Dec 2020 00:17:41
User entered empty.	Ruba Zanaid (b) (4)	08 Dec 2020 00:15:01
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:42:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Ruba Zanaid (b) (4)	08 Dec 2020 00:19:38
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Ruba Zanaid (b) (4)	08 Dec 2020 00:17:41
User entered empty.	(b) (4)	
	Ruba Zanaid (b) (4)	08 Dec 2020 00:15:01
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:42:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Ruba Zanaid (b) (4)	08 Dec 2020 00:19:38
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Ruba Zanaid (b) (4)	08 Dec 2020 00:17:41
User entered empty.	(b) (4)	
	Ruba Zanaid (b) (4)	08 Dec 2020 00:15:01
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:42:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	08 Dec 2020 00:17:41
User entered empty.	Ruba Zanaid (b) (4)	08 Dec 2020 00:15:01
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:42:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	08 Dec 2020 00:17:41
User entered empty.	Ruba Zanaid (b) (4)	08 Dec 2020 00:15:01
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:42:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	08 Dec 2020 00:17:41
User entered empty.	Ruba Zanaid (b) (4)	08 Dec 2020 00:15:01
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:42:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	08 Dec 2020 00:17:41
User entered empty.	Ruba Zanaid (b) (4)	08 Dec 2020 00:15:01
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:42:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	08 Dec 2020 00:17:41
User entered empty.	Ruba Zanaid (b) (4)	08 Dec 2020 00:15:01
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:42:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	08 Dec 2020 00:17:41
User entered empty.	Ruba Zanaid (b) (4)	08 Dec 2020 00:15:01
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:42:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	08 Dec 2020 00:17:41
User entered empty.	Ruba Zanaid (b) (4)	08 Dec 2020 00:15:01
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:42:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	08 Dec 2020 00:17:41
User entered empty.	Ruba Zanaid (b) (4)	08 Dec 2020 00:15:01
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:42:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	08 Dec 2020 00:17:41
User entered empty.	Ruba Zanaid (b) (4)	08 Dec 2020 00:15:01
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:42:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Day 9 (Day 9)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 19:58:09

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:42:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '8 Dec 2020'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 19:58:09

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:42:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '0'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 19:58:09

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:42:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '99'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 19:58:09

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:42:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
User entered '%'	System	08 Dec 2020 19:58:09

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:42:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '97.8' F	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 19:58:09

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:42:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Ruba Zanaid (b) (4)	08 Dec 2020 19:58:09
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:42:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 19:58:09

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:42:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 19:58:09

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:42:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 19:58:09

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:42:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Ruba Zanaid (b) (4)	08 Dec 2020 19:58:09
	(b) (4)	

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:42:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Ruba Zanaid (b) (4)	08 Dec 2020 19:58:09
	(b) (4)	

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:42:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Ruba Zanaid (b) (4)	08 Dec 2020 19:58:09
	(b) (4)	

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:42:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 19:58:09

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:42:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 19:58:09

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:42:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 19:58:09

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:42:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Ruba Zanaid (b) (4)	08 Dec 2020 19:58:09
	(b) (4)	

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:42:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Ruba Zanaid (b) (4)	08 Dec 2020 19:58:09
	(b) (4)	

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:42:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Ruba Zanaid (b) (4)	08 Dec 2020 19:58:09
	(b) (4)	

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:42:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Ruba Zanaid (b) (4)	08 Dec 2020 19:58:09
	(b) (4)	

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:42:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 19:58:09

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:42:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Ruba Zanaid (b) (4)	08 Dec 2020 19:58:09
	(b) (4)	

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:42:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Day 10 (Day 10)'	(b) (4) Matthew Pohlmeier (b) (4)	09 Dec 2020 21:59:46

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:42:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '09 Dec 2020'	(b) (4) Matthew Pohlmeier (b) (4)	09 Dec 2020 21:59:46

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:42:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '0'	(b) (4) Matthew Pohlmeier (b) (4)	09 Dec 2020 21:59:46

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:42:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '96'	(b) (4) Matthew Pohlmeier (b) (4)	09 Dec 2020 21:59:46

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:42:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
User entered '%'	System	09 Dec 2020 21:59:46

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:42:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '98.0' F	(b) (4) Matthew Pohlmeier (b) (4)	09 Dec 2020 21:59:46

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:42:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	09 Dec 2020 21:59:46

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:42:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	09 Dec 2020 21:59:46

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:42:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	09 Dec 2020 21:59:46

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:42:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	09 Dec 2020 21:59:46

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:42:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	09 Dec 2020 21:59:46

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:42:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	09 Dec 2020 21:59:46

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:42:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	09 Dec 2020 21:59:46

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:42:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	09 Dec 2020 21:59:46

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:42:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	09 Dec 2020 21:59:46

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:42:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	09 Dec 2020 21:59:46

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:42:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	09 Dec 2020 21:59:46

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:42:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	09 Dec 2020 21:59:46

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:42:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	09 Dec 2020 21:59:46

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:42:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	09 Dec 2020 21:59:46

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:42:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	09 Dec 2020 21:59:46

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:42:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	09 Dec 2020 21:59:46

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:42:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Day 11 (Day 11)'	(b) (4) Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:42:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '10 Dec 2020'	(b) (4) Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:42:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '0'	(b) (4) Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:42:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '100'	(b) (4) Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:42:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
User entered '%'	System	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:42:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '98.2' F	(b) (4) Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:42:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:42:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:42:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:42:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:42:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:42:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:42:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:42:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:42:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:42:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:42:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:42:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:42:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:42:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:42:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:42:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)'	(b) (4) Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:42:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Day 12 (Day 12)' reason for change:	(b) (4)	11 Dec 2020 19:10:24
Data Entry Error	Matthew Pohlmeier	11 Dec 2020 19:10:24
DataPoint activated with code reason code Data	(b) (4)	11 Dec 2020 19:08:57
required.	Matthew Pohlmeier	11 Dec 2020 19:08:57
DataPoint inactivated with code reason code Data not	(b) (4)	10 Dec 2020 22:38:08
required.	Matthew Pohlmeier	10 Dec 2020 22:38:08
User entered empty.	(b) (4)	10 Dec 2020 22:36:18
	Matthew Pohlmeier	10 Dec 2020 22:36:18
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:42:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Dec 2020 19:10:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Dec 2020 19:10:15
User entered '11 Dec 2020' reason for change: Data Entry Error	Matthew Pohlmeier (b) (4)	11 Dec 2020 19:10:15
DataPoint activated with code reason code Data required.	Matthew Pohlmeier (b) (4)	11 Dec 2020 19:08:57
DataPoint inactivated with code reason code Data not required.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:38:08
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 22:36:18
User entered empty.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:42:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
DataPoint activated with code reason code Data required.	(b) (4) Matthew Pohlmeier	11 Dec 2020 19:08:57
DataPoint inactivated with code reason code Data not required.	(b) (4) Matthew Pohlmeier	10 Dec 2020 22:38:08
User entered '0'	(b) (4) Matthew Pohlmeier	10 Dec 2020 22:36:18

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:42:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '98' reason for change: Data Entry Error	(b) (4)	11 Dec 2020 19:10:15
DataPoint activated with code reason code Data required.	Matthew Pohlmeier (b) (4)	11 Dec 2020 19:08:57
DataPoint inactivated with code reason code Data not required.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:38:08
User entered empty.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:42:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
User entered '%'	System	11 Dec 2020 19:10:15
DataPoint activated with code reason code Data required.	Matthew Pohlmeier	11 Dec 2020 19:08:57
DataPoint inactivated with code reason code Data not required.	(b) (4)	10 Dec 2020 22:38:08
User entered empty.	System	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:42:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '98.4' F reason for change: Data Entry Error	(b) (4)	11 Dec 2020 19:10:15
DataPoint activated with code reason code Data required.	Matthew Pohlmeier (b) (4)	11 Dec 2020 19:08:57
DataPoint inactivated with code reason code Data not required.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:38:08
User entered empty.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:42:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Dec 2020 19:10:15
DataPoint activated with code reason code Data required.	Matthew Pohlmeier (b) (4)	11 Dec 2020 19:08:57
DataPoint inactivated with code reason code Data not required.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:38:08
User entered empty.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:42:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Dec 2020 19:10:15
DataPoint activated with code reason code Data required.	Matthew Pohlmeier (b) (4)	11 Dec 2020 19:08:57
DataPoint inactivated with code reason code Data not required.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:38:08
User entered empty.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:42:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Dec 2020 19:10:15
DataPoint activated with code reason code Data required.	Matthew Pohlmeier (b) (4)	11 Dec 2020 19:08:57
DataPoint inactivated with code reason code Data not required.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:38:08
User entered empty.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:42:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Dec 2020 19:10:15
DataPoint activated with code reason code Data required.	Matthew Pohlmeier (b) (4)	11 Dec 2020 19:08:57
DataPoint inactivated with code reason code Data not required.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:38:08
User entered empty.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:42:05

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Dec 2020 19:10:15
DataPoint activated with code reason code Data required.	Matthew Pohlmeier (b) (4)	11 Dec 2020 19:08:57
DataPoint inactivated with code reason code Data not required.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:38:08
User entered empty.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:42:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4) (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)' reason for change: Data Entry Error	Matthew Pohlmeier (b) (4)	11 Dec 2020 19:10:15
DataPoint activated with code reason code Data required.	Matthew Pohlmeier (b) (4)	11 Dec 2020 19:08:57
DataPoint inactivated with code reason code Data not required.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:38:08
User entered empty.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:42:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Dec 2020 19:10:15
DataPoint activated with code reason code Data required.	Matthew Pohlmeier (b) (4)	11 Dec 2020 19:08:57
DataPoint inactivated with code reason code Data not required.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:38:08
User entered empty.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:42:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Dec 2020 19:10:15
DataPoint activated with code reason code Data required.	Matthew Pohlmeier (b) (4)	11 Dec 2020 19:08:57
DataPoint inactivated with code reason code Data not required.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:38:08
User entered empty.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:42:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Dec 2020 19:10:15
DataPoint activated with code reason code Data required.	Matthew Pohlmeier (b) (4)	11 Dec 2020 19:08:57
DataPoint inactivated with code reason code Data not required.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:38:08
User entered empty.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:42:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Dec 2020 19:10:15
DataPoint activated with code reason code Data required.	Matthew Pohlmeier (b) (4)	11 Dec 2020 19:08:57
DataPoint inactivated with code reason code Data not required.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:38:08
User entered empty.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:42:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Dec 2020 19:10:15
DataPoint activated with code reason code Data required.	Matthew Pohlmeier (b) (4)	11 Dec 2020 19:08:57
DataPoint inactivated with code reason code Data not required.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:38:08
User entered empty.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:42:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Dec 2020 19:10:15
DataPoint activated with code reason code Data required.	Matthew Pohlmeier (b) (4)	11 Dec 2020 19:08:57
DataPoint inactivated with code reason code Data not required.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:38:08
User entered empty.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:42:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Dec 2020 19:10:15
DataPoint activated with code reason code Data required.	Matthew Pohlmeier (b) (4)	11 Dec 2020 19:08:57
DataPoint inactivated with code reason code Data not required.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:38:08
User entered empty.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:42:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4) (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)' reason for change: Data Entry Error	Matthew Pohlmeier (b) (4)	11 Dec 2020 19:10:15
DataPoint activated with code reason code Data required.	Matthew Pohlmeier (b) (4)	11 Dec 2020 19:08:57
DataPoint inactivated with code reason code Data not required.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:38:08
User entered empty.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:42:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Dec 2020 19:10:15
DataPoint activated with code reason code Data required.	Matthew Pohlmeier (b) (4)	11 Dec 2020 19:08:57
DataPoint inactivated with code reason code Data not required.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:38:08
User entered empty.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:42:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:35
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	11 Dec 2020 19:10:15
DataPoint activated with code reason code Data required.	Matthew Pohlmeier (b) (4)	11 Dec 2020 19:08:57
DataPoint inactivated with code reason code Data not required.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:38:08
User entered empty.	Matthew Pohlmeier (b) (4)	10 Dec 2020 22:36:18

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:42:05

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:01
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:30:00
User entered '02 Dec 2020'	Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:05:10

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:42:05

[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 20:49:01
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:30:00
User entered 'Yes (Y)'	Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:05:10

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:42:05

[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 20:49:01
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:30:00
User entered 'No (N)'	Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:05:10

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:42:05

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:01
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:30:00
User entered '02 Dec 2020'	Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:05:10

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:42:05

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:01
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:30:00
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:05:10

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:42:05

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:01
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:30:00
User entered empty.	Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:05:10

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:42:05

[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 20:49:01
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:30:00
User entered 'No (N)'	Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:05:10

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:42:05

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:01
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:30:00
User entered empty.	Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:05:10

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:42:05

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:01
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:30:00
User entered empty.	Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:05:10

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:42:05

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:01
User entered '0'	System	03 Dec 2020 21:05:10

US3772187

Folder: Covid-19 Assessment 01 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:42:05

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:49:05
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:57:46
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	03 Dec 2020 21:05:21

US3772187

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:42:05

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:22
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	10 Feb 2021 20:31:12

US3772187

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:42:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:05
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12

US3772187

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:42:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:05
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12

US3772187

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:42:05

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:22
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	10 Feb 2021 20:31:12

US3772187

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:42:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:05
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12

US3772187

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:42:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:05
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12

US3772187

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:42:05

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:22
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	10 Feb 2021 20:31:12

US3772187

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:42:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:05
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12

US3772187

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:42:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:05
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12

US3772187

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:42:05

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:22
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	10 Feb 2021 20:31:12

US3772187

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:42:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:05
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12

US3772187

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:42:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:05
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12

US3772187

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:42:05

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:22
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	10 Feb 2021 20:31:12

US3772187

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:42:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:05
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12

US3772187

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:42:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:05
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12

US3772187

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:42:05

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:22
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	10 Feb 2021 20:31:12

US3772187

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:42:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:05
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12

US3772187

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:42:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:05
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12

US3772187

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:42:05

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:22
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	10 Feb 2021 20:31:12

US3772187

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:42:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:05
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12

US3772187

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:42:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:22
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:05
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12

US3772187

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:44
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:13
User entered 'Yes (Y)'	Matthew Pohlmeier (b) (4)	02 Dec 2020 20:18:25

US3772187

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:44
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:13
User entered '2 Dec 2020'	Matthew Pohlmeier (b) (4)	02 Dec 2020 20:18:25

US3772187

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

[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 08:05:44
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:13
User entered 'Clinic (Clinic)'	Matthew Pohlmeier (b) (4)	02 Dec 2020 20:18:25

US3772187

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:44
User entered 'SICKD1'	System	02 Dec 2020 20:18:25

US3772187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:51
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:19
User entered 'Yes (Y)'	Matthew Pohlmeier (b) (4)	02 Dec 2020 20:19:33

US3772187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:51
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:19
User entered '2 Dec 2020'	Matthew Pohlmeier (b) (4)	02 Dec 2020 20:19:33

US3772187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:51
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:19
User entered '11:20'	Matthew Pohlmeier (b) (4)	02 Dec 2020 20:19:33

US3772187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:51
User entered '2 Dec 2020 11:20'	System	02 Dec 2020 20:19:33

US3772187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:51
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:19
User entered missing code ND - Not Done.	Matthew Pohlmeier	02 Dec 2020 20:19:33
DataPoint set to visible.	(b) (4) System	02 Dec 2020 20:18:25

US3772187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:51
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:19
User entered missing code ND - Not Done.	Matthew Pohlmeier	02 Dec 2020 20:19:33
DataPoint set to visible.	(b) (4) System	02 Dec 2020 20:18:25

US3772187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:51
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:19
User entered '37.5' C	Matthew Pohlmeier (b) (4)	02 Dec 2020 20:19:33

US3772187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:51
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:19
User entered 'Oral (Oral)'	Matthew Pohlmeier (b) (4)	02 Dec 2020 20:19:33

US3772187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:51
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:19
User entered empty.	Matthew Pohlmeier (b) (4)	02 Dec 2020 20:19:33

US3772187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:51
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:19
User entered '85'	Matthew Pohlmeier (b) (4)	02 Dec 2020 20:19:33

US3772187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:51
User entered 'bpm'	System	02 Dec 2020 20:19:33

US3772187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:51
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:19
User entered '16'	Matthew Pohlmeier (b) (4)	02 Dec 2020 20:19:33

US3772187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:51
User entered 'breaths/min'	System	02 Dec 2020 20:19:33

US3772187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:51
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:19
User entered '125'	Matthew Pohlmeier (b) (4)	02 Dec 2020 20:19:33

US3772187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:51
User entered 'mmHg'	System	02 Dec 2020 20:19:33

US3772187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:51
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:19
User entered '85'	Matthew Pohlmeier (b) (4)	02 Dec 2020 20:19:33

US3772187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:51
User entered 'mmHg'	System	02 Dec 2020 20:19:33

US3772187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:51

US3772187

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:51

US3772187

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:42:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:24
User entered 'Yes (Y)'	Matthew Pohlmeier (b) (4)	02 Dec 2020 20:19:43

US3772187

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:42:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:05:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:24
User entered '2 Dec 2020'	Matthew Pohlmeier (b) (4)	02 Dec 2020 20:19:43

US3772187

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 09:42:05

[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 08:06:02
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:01:04
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 02 DEC 2020 is recorded under Illness Visit Day 1 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) (4), (b) (6)	15 Jan 2021 14:21:36
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 02 DEC 2020 is recorded under Illness Visit Day 1 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 'All samples shown as received by lab in PPD portal' (Site from DM).	Emily Crews (b) (4) (b) (4)	05 Jan 2021 00:22:49
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 02 DEC 2020 is recorded under Illness Visit Day 1 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)	10 Dec 2020 08:49:47
User entered 'Yes (Y)'	Matthew Pohlmeier (b) (4)	02 Dec 2020 20:19:51

US3772187

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 09:42:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:06:02
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:34
User entered '2 Dec 2020'	Matthew Pohlmeier (b) (4)	02 Dec 2020 20:19:51

US3772187

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

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:13
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:28:13

US3772187

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

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:13
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '28 Jan 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:28:13

US3772187

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

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:13
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Clinic (Clinic)'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:28:13

US3772187

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

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered 'UNBLND_DECIDE'	System	28 Jan 2021 23:28:13

US3772187

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

Form: Unblinding

Generated On: 10 Jun 2021 09:42:05

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:18
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '28 Jan 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:28:38

US3772187

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

Form: Unblinding

Generated On: 10 Jun 2021 09:42:05

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:23:18

US3772187

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

Form: Unblinding

Generated On: 10 Jun 2021 09:42:05

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:18
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:28:38

US3772187

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

Form: Unblinding

Generated On: 10 Jun 2021 09:42:05

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:23:18

US3772187

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

Form: Unblinding

Generated On: 10 Jun 2021 09:42:05

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:18
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '28 Jan 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:28:38

US3772187

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

Form: Unblinding

Generated On: 10 Jun 2021 09:42:05

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:18
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Placebo (Placebo)'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:28:38

US3772187

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

Form: Unblinding

Generated On: 10 Jun 2021 09:42:05

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:18
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Placebo (Placebo)'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:28:38

US3772187

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

Form: Unblinding

Generated On: 10 Jun 2021 09:42:05

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:18
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Placebo (Placebo)'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:28:38

US3772187

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

Form: Unblinding

Generated On: 10 Jun 2021 09:42:05

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:18
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:28:38

US3772187

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

Form: Unblinding

Generated On: 10 Jun 2021 09:42:05

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered '1'	System	28 Jan 2021 23:28:38

US3772187

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

Form: Unblinding

Generated On: 10 Jun 2021 09:42:05

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered '1'	System	28 Jan 2021 23:28:38

US3772187

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:42:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:23
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered missing code ND - Not Done.	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:42:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:23
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered missing code ND - Not Done.	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:42:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered empty.	System	28 Jan 2021 23:29:32
DataPoint set to visible.	System	28 Jan 2021 23:28:38

US3772187

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:42:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:23
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered missing code ND - Not Done.	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:42:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:23
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered missing code ND - Not Done.	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:42:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered empty.	System	28 Jan 2021 23:29:32
DataPoint set to visible.	System	28 Jan 2021 23:28:38

US3772187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User accepted default value 'Pre-Dose (PREDOSE)'	Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:23
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:23
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '28 Jan 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:23
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '12:40'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered '28 Jan 2021 12:40'	System	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:23
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '36.6' C	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:23
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Oral (Oral)'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:23
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:23
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '65'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered 'bpm'	System	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:23
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '16'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered 'breaths/min'	System	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:23
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '117'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered 'mmHg'	System	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:23
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '74'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered 'mmHg'	System	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:42:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:23
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered missing code ND - Not Done.	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:42:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:23
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered missing code ND - Not Done.	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:42:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered empty.	System	28 Jan 2021 23:29:32
DataPoint set to visible.	System	28 Jan 2021 23:28:38

US3772187

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User accepted default value 'Post-Dose (POSTDOSE)'	Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:23
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:23
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '28 Jan 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:23
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '14:15'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered '28 Jan 2021 14:15'	System	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:23
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '36.7' C	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:23
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Oral (Oral)'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:23
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:23
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '65'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered 'bpm'	System	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:23
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '17'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered 'breaths/min'	System	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:23
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '130'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered 'mmHg'	System	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:23
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '86'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:29:32

US3772187

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered 'mmHg'	System	28 Jan 2021 23:29:32

US3772187

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:42:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:28
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:29:43

US3772187

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:42:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:28
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '28 Jan 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:29:43

US3772187

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

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:34
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:30:21

US3772187

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

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:34
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:30:21

US3772187

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

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:34
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:30:21

US3772187

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

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered 'mRNA-1273'	System	28 Jan 2021 23:30:21
DataPoint set to visible.	System	28 Jan 2021 23:28:38

US3772187

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

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:34
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '28 Jan 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:30:21

US3772187

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

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:34
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '13:43'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:30:21

US3772187

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

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered '28 Jan 2021 13:43'	System	28 Jan 2021 23:30:21

US3772187

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

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:34
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Left Arm (LEFT ARM)'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:30:21

US3772187

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

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:34
User entered 'ONCE'	System	28 Jan 2021 23:30:21

US3772187

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

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered 'INTRAMUSCULAR'	System	28 Jan 2021 23:30:21

US3772187

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:42:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:39
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:30:37

US3772187

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:42:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:39
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-Query: Thank you for the response. Since the sample is still missing in PPD labs, kindly provide Accession number and shipping details for sample dated 28JAN2021 under OL-D1 Visit in query response to confirm with GCL records.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 11:18:23
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-Query: Thank you for the response. Since the sample is still missing in PPD labs, kindly provide Accession number and shipping details for sample dated 28JAN2021 under OL-D1 Visit in query response to confirm with GCL records.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 10:24:13
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28JAN2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 10:24:13
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28JAN2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you.' answered with 'All samples were shipped from site 15Feb2021' (Site from DM).	Sarah Sandberg (b) (4) (b) (4)	16 Feb 2021 16:17:07

US3772187

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:42:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28JAN2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you.' (Site from DM). User entered '28 Jan 2021'	(b) (4), (b) (6)	16 Feb 2021 11:44:00
	Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:30:37

US3772187

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:42:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:39
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '12:15'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:30:37

US3772187

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:42:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered '28 Jan 2021 12:15'	System	28 Jan 2021 23:30:37

US3772187

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:42:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:43
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:30:48

US3772187

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:42:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:43
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '28 Jan 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:30:48

US3772187

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:42:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:43
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '12:18'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:30:48

US3772187

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:42:05

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered '28 Jan 2021 12:18'	System	28 Jan 2021 23:30:48

US3772187

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

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:48
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:30:52

US3772187

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

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered '1'	System	28 Jan 2021 23:30:52

US3772187

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:55
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:00:56
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	06 Feb 2021 00:06:17

US3772187

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:55
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:00:56
User entered '05 Feb 2021'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	06 Feb 2021 00:06:17

US3772187

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:55
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:00:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	06 Feb 2021 00:06:17

US3772187

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:46:55
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:00:56
User entered empty.	(b) (4) Sarah Sandberg (b) (4) (b) (4)	06 Feb 2021 00:06:17

US3772187

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:00
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	06 Feb 2021 00:06:23

US3772187

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered '1'	System	06 Feb 2021 00:06:23

US3772187

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered '1'	System	06 Feb 2021 00:06:23
DataPoint set to visible.	System	06 Feb 2021 00:06:23

US3772187

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:06
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:16:47

US3772187

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:06
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered '01 Mar 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:16:47

US3772187

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:06
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'Clinic (Clinic)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:16:47

US3772187

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered 'OLD29'	System	01 Mar 2021 22:16:47

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User accepted default value 'Pre-Dose (PREDOSE)'	Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:11
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:11
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered '01 Mar 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:11
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered '08:40'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered '01 Mar 2021 08:40'	System	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:11
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered '36.2' C	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:11
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'Oral (Oral)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:11
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:11
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered '75'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered 'bpm'	System	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:11
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered '18'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered 'breaths/min'	System	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:11
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered '118'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered 'mmHg'	System	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:11
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered '80'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:42:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered 'mmHg'	System	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User accepted default value 'Post-Dose (POSTDOSE)'	Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:11
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:11
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered '01 Mar 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:11
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered '10:30'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered '01 Mar 2021 10:30'	System	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:11
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered '36.0' C	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:11
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'Oral (Oral)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:11
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:11
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered '72'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered 'bpm'	System	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:11
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered '17'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered 'breaths/min'	System	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:11
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered '118'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered 'mmHg'	System	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:11
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered '76'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:42:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered 'mmHg'	System	01 Mar 2021 22:17:40

US3772187

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:42:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:15
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:17:49

US3772187

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:42:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:15
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered '01 Mar 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:17:49

US3772187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:22
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:18:07

US3772187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:22
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:18:07

US3772187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:22
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:18:07

US3772187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered 'mRNA-1273'	System	01 Mar 2021 22:18:07
DataPoint set to visible.	System	06 Feb 2021 00:06:23

US3772187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:22
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered '01 Mar 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:18:07

US3772187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:22
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered '09:49'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:18:07

US3772187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered '01 Mar 2021 09:49'	System	01 Mar 2021 22:18:07

US3772187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:22
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'Left Arm (LEFT ARM)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:18:07

US3772187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:22
User entered 'ONCE'	System	01 Mar 2021 22:18:07

US3772187

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:42:05

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered 'INTRAMUSCULAR'	System	01 Mar 2021 22:18:07

US3772187

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:26
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:18:11

US3772187

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered 'I'	System	01 Mar 2021 22:18:11

US3772187

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:32
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:00:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:15:30

US3772187

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:32
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:00:56
User entered '8 Mar 2021'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:15:30

US3772187

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:32
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:00:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:15:30

US3772187

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:42:05

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:32
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:00:56
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:15:30

US3772187

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:36
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 20:15:35

US3772187

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:42:05

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:36
User entered 'I'	System	08 Mar 2021 20:15:35

US3772187

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:41
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:37:25
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4)	01 Apr 2021 15:47:47

US3772187

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:41
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:37:25
User entered '31 Mar 2021'	(b) (4) Emily Crews (b) (4)	01 Apr 2021 15:47:47

US3772187

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:41
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:37:25
User entered 'Clinic (Clinic)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 15:47:47

US3772187

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:42:05

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	01 Apr 2021 15:47:47

US3772187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:46
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:37:25
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4)	01 Apr 2021 15:48:32

US3772187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:46
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:37:25
User entered '31 Mar 2021'	(b) (4) Emily Crews (b) (4)	01 Apr 2021 15:48:32

US3772187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:46
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:37:25
User entered '09:48'	(b) (4) Emily Crews (b) (4)	01 Apr 2021 15:48:32

US3772187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
User entered '31 Mar 2021 09:48'	System	01 Apr 2021 15:48:32

US3772187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:46
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:37:25
User entered '36.9' C	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 15:48:32

US3772187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:46
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:37:25
User entered 'Oral (Oral)'	(b) (4) Emily Crews (b) (4)	01 Apr 2021 15:48:32

US3772187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:46
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:37:25
User entered empty.	(b) (4) Emily Crews (b) (4)	01 Apr 2021 15:48:32

US3772187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:46
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:37:25
User entered '75'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 15:48:32

US3772187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Apr 2021 15:48:32

US3772187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:46
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:37:25
User entered '15'	(b) (4) Emily Crews (b) (4)	01 Apr 2021 15:48:32

US3772187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Apr 2021 15:48:32

US3772187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:46
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:37:25
User entered '111'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 15:48:32

US3772187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 15:48:32

US3772187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:46
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:37:25
User entered '75'	(b) (4) Emily Crews (b) (4)	01 Apr 2021 15:48:32

US3772187

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:42:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 15:48:32

US3772187

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:42:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:51
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:37:25
User entered 'No (N)'	(b) (4) Emily Crews (b) (4)	01 Apr 2021 15:48:46

US3772187

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:42:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:51
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:37:25
User entered empty.	(b) (4) Emily Crews (b) (4)	01 Apr 2021 15:48:46

US3772187

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:42:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:58
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:37:25
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4)	01 Apr 2021 15:48:59

US3772187

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:42:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:58
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:37:25
User entered '31 Mar 2021'	(b) (4) Emily Crews (b) (4)	01 Apr 2021 15:48:59

US3772187

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:42:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:47:58
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:37:25
User entered '09:51'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 15:48:59

US3772187

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:42:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '31 Mar 2021 09:51'	System	01 Apr 2021 15:48:59

US3772187

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:42:05

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:47:23
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:53
User entered 'Yes (Y)'	Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 00:20:19

US3772187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 18:40:22
User entered 'USA-US107-2020-mRNA-1273-P301000008'	System	08 Dec 2020 15:25:12
User entered 'New'	(b) (4), (b) (6)	08 Dec 2020 15:25:12

US3772187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\23.0.	Coder Import (b) (4)	08 Dec 2020 00:27:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Dec 2020 00:27:50
Data point term sent to Coder	System	08 Dec 2020 00:27:28
User entered 'Appendicitis'	Ruba Zanaid (b) (4)	08 Dec 2020 00:27:13

US3772187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered 'Yes (Y)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 00:27:13

US3772187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered 'No (N)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 00:27:13

US3772187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered 'No (N)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 00:27:13

US3772187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered '7 Dec 2020'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 00:27:13

US3772187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	08 Dec 2020 00:28:31
User entered empty; reason for change Data Entry Error	Ruba Zanaid (b) (4)	08 Dec 2020 00:28:31
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	08 Dec 2020 00:27:13
User entered '14:30'	Ruba Zanaid (b) (4)	08 Dec 2020 00:27:13

US3772187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Dec 2020 00:28:31
User entered '7 Dec 2020 14:30'	System	08 Dec 2020 00:27:13

US3772187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	08 Dec 2020 19:23:26
User entered 'No (N)' reason for change: Data Entry Error	System	08 Dec 2020 19:23:26
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	Ruba Zanaid (b) (4)	08 Dec 2020 19:23:26
User entered 'Yes (Y)'	(b) (4)	08 Dec 2020 19:22:55
	Ruba Zanaid (b) (4)	08 Dec 2020 00:27:13
	(b) (4)	

US3772187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) System	08 Dec 2020 19:25:20
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	08 Dec 2020 19:25:20
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	08 Dec 2020 19:22:55
User entered '7 Dec 2020' reason for change: Data Entry Error	Ruba Zanaid (b) (4)	08 Dec 2020 19:22:55
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 00:27:13

US3772187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4) (b) (4)	13 Mar 2021 01:20:53
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	08 Dec 2020 19:23:59
User entered empty; reason for change Data Entry Error	Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 19:23:59
User closed query 'Ongoing is Yes, but End Time is provided. Please correct.' (Site from System).	System	08 Dec 2020 19:23:26
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	08 Dec 2020 19:23:26
User opened query 'Ongoing is Yes, but End Time is provided. Please correct.' (Site from System).	System	08 Dec 2020 19:22:55
User entered '20:00' reason for change: Data Entry Error	Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 19:22:55
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 00:27:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Dec 2020 19:23:59
User entered '7 Dec 2020 20:00'	System	08 Dec 2020 19:22:55
User entered empty.	System	08 Dec 2020 00:27:13

US3772187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	(b) (4) Ruba Zanaid (b) (4)	08 Dec 2020 00:36:03
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Ruba Zanaid (b) (4)	08 Dec 2020 00:27:13

US3772187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4) System	08 Dec 2020 18:43:24
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	08 Dec 2020 00:34:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Ruba Zanaid (b) (4)	08 Dec 2020 00:34:08
User entered 'No (N)'	(b) (4) Ruba Zanaid (b) (4)	08 Dec 2020 00:27:13

US3772187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered '0'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 00:27:13

US3772187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered '0'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 00:27:13

US3772187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Dec 2020 07:47:45
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 'Admission date is entered.' (Site from System).	Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 18:44:04
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		08 Dec 2020 18:43:24
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		08 Dec 2020 18:43:24
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	08 Dec 2020 18:43:24
User entered '1' reason for change: Data Entry Error	Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 18:43:24
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	08 Dec 2020 00:27:13
User entered '0'	Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 00:27:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered '7 Dec 2020' reason for change: Data Entry Error	(b) (4)	08 Dec 2020 00:34:08
User entered empty.	Ruba Zanaid (b) (4)	08 Dec 2020 00:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 00:27:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Ruba Zanaid (b) (4)	08 Dec 2020 00:34:08
User closed query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	08 Dec 2020 00:28:08
Query 'Admitted to ICU?' is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		08 Dec 2020 00:28:08
User entered 'No (N)' reason for change: Data Entry Error	Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 00:28:08
User opened query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	08 Dec 2020 00:27:13
User entered 'Unknown (UNK)'	Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 00:27:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	(b) (4)	08 Dec 2020 18:44:46
Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' answered by data change (Site from System).	System	08 Dec 2020 18:44:46
User entered '1' reason for change: Data Entry Error	Ruba Zanaid (b) (4)	08 Dec 2020 18:44:46
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	(b) (4)	08 Dec 2020 18:43:24
User entered empty.	System	08 Dec 2020 18:43:24
	Ruba Zanaid (b) (4)	08 Dec 2020 00:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered '0'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 00:27:13

US3772187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered '0'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 00:27:13

US3772187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered '0'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 00:27:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered 'Not Related (NOT RELATED)'	(b) (4) Ruba Zanaid (b) (4)	08 Dec 2020 00:27:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered 'Not Related (NOT RELATED)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 00:27:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Dec 2020 00:28:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Dec 2020 00:28:08
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Ruba Zanaid (b) (4)	08 Dec 2020 00:28:08
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Dec 2020 00:27:13
User entered empty.	System	08 Dec 2020 00:27:13
	Ruba Zanaid (b) (4)	08 Dec 2020 00:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Procedure (#1) recorded that matches this AE during this timeframe. Please review and update this field. '(Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:41:12
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Procedure (#1) 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)	22 Jan 2021 19:49:40
User entered '0' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	22 Jan 2021 19:48:56
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Procedure (#1) recorded that matches this AE during this timeframe. Please review and update this field. '(Site from DM).	(b) (4), (b) (6)	18 Jan 2021 07:09:12
User entered '1'	Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 00:27:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered '1' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	05 Feb 2021 17:54:30
User entered '0'	(b) (4) Ruba Zanaid (b) (4)	08 Dec 2020 00:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered '1' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	22 Jan 2021 19:48:56
User entered '0'	(b) (4) Ruba Zanaid (b) (4)	08 Dec 2020 00:27:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Ruba Zanaid (b) (4)	08 Dec 2020 19:25:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	
	Ruba Zanaid (b) (4)	08 Dec 2020 00:27:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 00:27:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User closed query 'PV Query: Please consider reporting additional SAE Intraabdominal abscess.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 19:26:59
User closed query 'PV Query: Please consider updating event term to Ruptured appendicitis.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 19:26:45
Query 'PV Query: Please consider reporting additional SAE Intraabdominal abscess.' answered with 'Per PI this will be reported as an AE due to the SAE of Appendicitis' (Site from Safety).	Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:10:18
Query 'PV Query: Please consider updating event term to Ruptured appendicitis.' answered with 'Per PI Dx of Appendicitis will remain the same ' (Site from Safety).	Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:09:57
User opened query 'PV Query: Please consider reporting additional SAE Intraabdominal abscess.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 19:26:38
User opened query 'PV Query: Please consider updating event term to Ruptured appendicitis.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 19:26:21
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 18:40:16
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 18:40:08
User closed query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 18:39:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'From the medical report: Subjective: patient with no significant PMH presents with abdominal pain + cramping x 1 week, admitted for ruptured appendicitis and fever. Lab Results: WBC: 16.1 K/uL H on 07-DEC-2020 Neuts: 79% H on 07-DEC-2020 WBC : 9.6 on 11-DEC-2020 Abdomen CT: There is an approximately 5 cm area of fluid with peripheral rim enhancement located between the ascending colon, the right psoas muscle and the right iliacus muscle. These findings are consistent with extensive changes of appendicitis with a ruptured appendix and a contained rupture or abscess located between the right psoas muscle and the right iliacus muscle. Procedure: 1- Diagnostic laparoscopy 2- Open appendectomy with drainage of abscess. ' (Site from Safety).	Ruba Zanaid (b) (4) (b) (4)	15 Dec 2020 22:54:21
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'No Covid testing were included in the medical records received. ' (Site from Safety).	Ruba Zanaid (b) (4) (b) (4)	15 Dec 2020 21:59:54
Query 'PV Query: Please provide the hospital discharge date when available. ' answered with '12-DEC-2020 per medical records' (Site from Safety).	Ruba Zanaid (b) (4) (b) (4)	15 Dec 2020 21:59:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

[Narrative](#)

Audit	User	Time (GMT)
User entered 'DURING SUBJECT TELEMED CALL FOR TODAY , SUBJECT REPORTED THAT THEY ARE AT THE HOSPITAL AT THE MOMENT WHERE THEY GOT DIAGNOSED WITH APPENDICITIS . ON 08 DEC2020 SITE CALLED THE SUBJECT IN WHICH THE SUBJECT REPORTED HAVING UNDERGONE APPENDECTOMY ON 07 DEC2020. SITE REQUESTED MEDICAL RECORDS FOR THE SUBJECT. Medical records received and Subject was recharged for the hospital on 12-DEC-2020. Medical records confirmed appendectomy has been done.' reason for change: Data Entry Error	Ruba Zanaid (b) (4) (b) (4)	15 Dec 2020 21:58:45
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 15:25:49
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 15:25:03
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 15:24:27
User entered 'DURING SUBJECT TELEMED CALL FOR TODAY , SUBJECT REPORTED THAT THEY ARE AT THE HOSPITAL AT THE MOMENT WHERE THEY GOT DIAGNOSED WITH APPENDICITIS . On 08 Dec2020 site called the subject in which the subject reported having undergone appendectomy on 07 DEC2020. Site requested medical records for the subject.' reason for change: Data Entry Error	Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 19:28:03
User entered 'During subject telemed call for today , subject reported that they are at the hospital at the moment where they got diagnosed with Appendicitis .'	Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 00:27:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	08 Dec 2020 00:34:08
User entered '0'	System	08 Dec 2020 00:27:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	08 Dec 2020 00:27:13

US3772187

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:42:05

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Dec 2020 00:34:08
User entered '0'	System	08 Dec 2020 00:27:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User coded data point as SOC: Infections and infestations, HLG: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendiceal abscess, LLT: Appendiceal abscess - version MedDRA\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Jan 2021 17:51:43
Data point term sent to Coder	(b) (4)	
User entered 'Appendiceal Abscess'	Coder Import (b) (4)	07 Jan 2021 17:51:43
	(b) (4)	
	System	07 Jan 2021 17:51:22
	Emily Crews (b) (4)	07 Jan 2021 17:51:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered '07 Dec 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:11

US3772187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
User entered empty.	System	07 Jan 2021 17:51:11

US3772187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:11

US3772187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered '07 Dec 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:11

US3772187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:11

US3772187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
User entered empty.	System	07 Jan 2021 17:51:11

US3772187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:11

US3772187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:11

US3772187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:11

US3772187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:11

US3772187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:11

US3772187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:11

US3772187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:11

US3772187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:11

US3772187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:11

US3772187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:11

US3772187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:11

US3772187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:11

US3772187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered 'Not Related (NOT RELATED)'	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:11

US3772187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered 'Not Related (NOT RELATED)'	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:11

US3772187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4) (b) (4)	13 Mar 2021 01:20:53
User entered 'Not Applicable (NOT APPLICABLE)'	Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:11

US3772187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered '1'	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:11

US3772187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

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 04:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:11

US3772187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:03:29
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:20:53
User entered 'During the review of medical records it was noted the subject had an Appendiceal Abscess caused by their Appendicitis. Abscess was drained during the Appendectomy Procedure.'	(b) (4) Emily Crews (b) (4)	07 Jan 2021 17:51:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
User entered '0'	System	07 Jan 2021 17:51:11

US3772187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56
User entered '1'	System	07 Jan 2021 17:51:11

US3772187

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:42:05

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:26:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:42:05

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:47:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:48:27
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	31 Aug 2020 18:00:27

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:42:05

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
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 - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 22:56:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 22:56:50
Data point term sent to Coder User entered 'Ibuprofen'	System Sarah Sandberg (b) (4)	09 Sep 2020 22:55:43 09 Sep 2020 22:54:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:42:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4)	09 Sep 2020 22:54:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:42:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
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 THE 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 THE INJECTION SITE did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:32:46
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 THE 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 THE INJECTION SITE did not meet the AE reporting criteria.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 19:27:38

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:42:05

[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 THE 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 THE INJECTION SITE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 08:42:40
User entered 'Pain at the injection site'	Sarah Sandberg (b) (4) (b) (4)	09 Sep 2020 22:54:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:42:05

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '800'	(b) (4) Sarah Sandberg (b) (4)	09 Sep 2020 22:54:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:42:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'mg (mg)'	(b) (4) Sarah Sandberg (b) (4)	09 Sep 2020 22:54:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:42:05

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	09 Sep 2020 22:54:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:42:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'once daily (QD)'	(b) (4) Sarah Sandberg (b) (4)	09 Sep 2020 22:54:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:42:05

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	09 Sep 2020 22:54:42

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:42:05

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Oral (ORAL)'	(b) (4) Sarah Sandberg (b) (4)	09 Sep 2020 22:54:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:42:05

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	09 Sep 2020 22:54:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:42:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '01 Sep 2020'	(b) (4) Sarah Sandberg (b) (4)	09 Sep 2020 22:54:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:42:05

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '0'	(b) (4) Sarah Sandberg (b) (4)	09 Sep 2020 22:54:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:42:05

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4)	09 Sep 2020 22:54:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:42:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '01 Sep 2020'	(b) (4) Sarah Sandberg (b) (4)	09 Sep 2020 22:54:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:42:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:30:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:27:29
User entered 'Yes (Y)'	Sarah Sandberg (b) (4) (b) (4)	09 Sep 2020 22:54:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:42:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 22:54:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:42:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 22:54:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:42:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 22:54:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:42:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:22
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
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 - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Oct 2020 20:13:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 20:13:18
Data point term sent to Coder	System	07 Oct 2020 19:29:45
User entered 'Ibuprofen'	(b) (4), (b) (6)	07 Oct 2020 19:29:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:42:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:22
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:29:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:42:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:22
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
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 HEADACHE 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 HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:47:38
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE 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 HEADACHE did not meet the AE reporting criteria. ' answered with 'Subject had their second injection on 30-SEP-2020 therefore Headache reported on this form is considered a solicited systemic adverse reaction and it did NOT meet the criteria of MAAE, SAE or withdrawal from the study.' (Site from DM).	Ruba Zanaid (b) (4) (b) (4)	09 Dec 2020 17:01:02

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:42:05

[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 HEADACHE 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 HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 16:11:29
User entered 'Headache'	(b) (4), (b) (6)	07 Oct 2020 19:29:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:42:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:22
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '400'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:29:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:42:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:22
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:29:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:42:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:22
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:29:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:42:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:22
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	07 Oct 2020 19:30:20
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	07 Oct 2020 19:30:20
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	07 Oct 2020 19:29:53
User entered 'once (ONCE)'	(b) (4), (b) (6)	07 Oct 2020 19:29:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:42:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:22
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:29:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:42:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:22
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Oct 2020 19:29:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:42:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:22
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:29:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:42:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:22
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '2 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:30:20
User entered '7 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 19:29:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:42:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:22
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:29:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:42:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:22
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:29:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:42:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:22
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User closed query 'End date is prior to start date. Please correct.' (Site from System).	(b) (4)	07 Oct 2020 19:30:20
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	07 Oct 2020 19:29:53
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	07 Oct 2020 19:29:53
User entered '2 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:29:53
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	07 Oct 2020 19:29:42
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:29:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:42:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:22
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 19:29:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:42:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:22
User entered empty.	System	07 Oct 2020 19:29:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:42:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:22
User entered empty.	System	07 Oct 2020 19:29:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:42:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:22
User entered empty.	System	07 Oct 2020 19:29:42

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:42:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	02 Dec 2020 20:16:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	02 Dec 2020 20:16:46
Data point term sent to Coder	System	02 Dec 2020 20:16:05
User entered 'Tylenol'	Matthew Pohlmeier (b) (4)	02 Dec 2020 20:15:16

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:42:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'No (N)'	(b) (4) Matthew Pohlmeier (b) (4)	02 Dec 2020 20:15:16

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:42:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
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)	09 Feb 2021 03:40:10
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'This is in regards to COVID symptoms ' (Site from DM).	Emily Crews (b) (4) (b) (4)	05 Feb 2021 17:48:54
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)	27 Jan 2021 09:29:53
User entered 'Myalgia Abdominal Obliques'	Matthew Pohlmeier (b) (4)	02 Dec 2020 20:15:16

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:42:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '1000'	(b) (4) Matthew Pohlmeier (b) (4)	02 Dec 2020 20:15:16

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:42:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'mg (mg)'	(b) (4) Matthew Pohlmeier (b) (4)	02 Dec 2020 20:15:16

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:42:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered empty.	(b) (4) Matthew Pohlmeier (b) (4)	02 Dec 2020 20:15:16

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:42:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'twice daily (BID)'	(b) (4) Matthew Pohlmeier (b) (4)	02 Dec 2020 20:15:16

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:42:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered empty.	(b) (4) Matthew Pohlmeier (b) (4)	02 Dec 2020 20:15:16

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:42:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Oral (ORAL)'	(b) (4) Matthew Pohlmeier (b) (4)	02 Dec 2020 20:15:16

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:42:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered empty.	(b) (4) Matthew Pohlmeier (b) (4)	02 Dec 2020 20:15:16

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:42:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '01 Dec 2020'	(b) (4) Matthew Pohlmeier (b) (4)	02 Dec 2020 20:15:16

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:42:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '0'	(b) (4) Matthew Pohlmeier (b) (4)	02 Dec 2020 20:15:16

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:42:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'No (N)'	(b) (4) Matthew Pohlmeier (b) (4)	02 Dec 2020 20:15:16

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:42:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '02 Dec 2020'	(b) (4) Matthew Pohlmeier (b) (4)	02 Dec 2020 20:15:16

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:42:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'No (N)'	(b) (4) Matthew Pohlmeier (b) (4)	02 Dec 2020 20:15:16

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:42:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:54
User entered '2'	System	02 Dec 2020 20:15:16

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:42:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:54
User entered '1'	System	02 Dec 2020 20:15:16

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:42:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:54
User entered '804 (804)'	System	02 Dec 2020 20:15:16

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:42:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Dec 2020 18:14:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Dec 2020 18:14:05
Data point term sent to Coder User entered 'Norco'	System Ruba Zanaid (b) (4) (b) (4)	09 Dec 2020 18:12:49 09 Dec 2020 18:12:49

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:42:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'No (N)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	09 Dec 2020 18:12:49

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:42:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Post appendectomy'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	09 Dec 2020 18:12:49

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:42:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '10/325'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	09 Dec 2020 18:12:49

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:42:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'mg (mg)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	09 Dec 2020 18:12:49

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:42:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	09 Dec 2020 18:12:49

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:42:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'as needed (PRN)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	09 Dec 2020 18:12:49

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:42:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	09 Dec 2020 18:12:49

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:42:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Oral (ORAL)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	09 Dec 2020 18:12:49

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:42:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	09 Dec 2020 18:12:49

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:42:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '8 Dec 2020'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	09 Dec 2020 18:12:49

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:42:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '0'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	09 Dec 2020 18:12:49

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:42:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User closed query 'Per DM CLR: Please confirm if medication is ongoing, update end date if applicable or provide confirmation if ongoing' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:12:29
Query 'Per DM CLR: Please confirm if medication is ongoing, update end date if applicable or provide confirmation if ongoing' answered with 'Updated' (Site from DM).	Emily Crews (b) (4) (b) (4)	05 Feb 2021 17:53:37
User entered 'No (N)' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	05 Feb 2021 17:49:33
User opened query 'Per DM CLR: Please confirm if medication is ongoing, update end date if applicable or provide confirmation if ongoing' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 09:30:20
Query 'Source indicate stop date of 11Dec2020' canceled (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:53:59
User opened query 'Source indicate stop date of 11Dec2020' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:47:59
User entered 'Yes (Y)'	Ruba Zanaid (b) (4) (b) (4)	09 Dec 2020 18:12:49

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:42:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4) (b) (4)	24 Mar 2021 18:53:18
User entered '20 Dec 2020' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	05 Feb 2021 17:49:33
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	09 Dec 2020 18:12:49

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:42:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'No (N)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	09 Dec 2020 18:12:49

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:42:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:11
User entered empty.	System	09 Dec 2020 18:12:49

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:42:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:11
User entered empty.	System	09 Dec 2020 18:12:49

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:42:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:49:11
User entered empty.	System	09 Dec 2020 18:12:49

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:42:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:50:41
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	09 Dec 2020 18:19:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Dec 2020 18:19:19
Data point term sent to Coder User entered 'Zosyn'	System Ruba Zanaid (b) (4)	09 Dec 2020 18:17:56 09 Dec 2020 18:17:08

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:42:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:50:41
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Yes (Y)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	09 Dec 2020 18:17:08

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:42:05

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:50:41
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Post appendectomy infection prophylaxis'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	09 Dec 2020 18:17:08

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:42:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:50:41
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '4.5/100'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	09 Dec 2020 18:17:08

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:42:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:50:41
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'mL (mL)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	09 Dec 2020 18:17:08

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:42:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:50:41
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	09 Dec 2020 18:17:08

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:42:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:50:41
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'four times daily (QID)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	09 Dec 2020 18:17:08

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:42:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:50:41
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	09 Dec 2020 18:17:08

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:42:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:50:41
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	09 Dec 2020 18:17:08

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:42:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:50:41
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	09 Dec 2020 18:17:08

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:42:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:50:41
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '8 Dec 2020'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	09 Dec 2020 18:17:08

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:42:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:50:41
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '0'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	09 Dec 2020 18:17:08

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:42:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:50:41
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	15 Dec 2020 22:57:17
User entered 'Yes (Y)'	Ruba Zanaid (b) (4)	09 Dec 2020 18:17:08
	(b) (4)	

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:42:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:50:41
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '11 Dec 2020' reason for change: Data Entry Error	(b) (4)	15 Dec 2020 22:57:17
User entered empty.	Ruba Zanaid (b) (4)	09 Dec 2020 18:17:08
	(b) (4)	

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:42:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:50:41
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'No (N)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	09 Dec 2020 18:17:08

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:42:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:50:41
User entered '4'	System	09 Dec 2020 18:17:08

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:42:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:50:41
User entered '1'	System	09 Dec 2020 18:17:08

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:42:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:50:41
User entered '804 (804)'	System	09 Dec 2020 18:17:08

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:42:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	16 Dec 2020 09:40:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 09:40:52
Data point term sent to Coder	System	15 Dec 2020 22:59:39
User entered 'Ciprofloxacin'	Ruba Zanaid (b) (4) (b) (4)	15 Dec 2020 22:58:51

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:42:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Yes (Y)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	15 Dec 2020 22:58:51

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:42:05

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Post appendectomy infection prophylaxis'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	15 Dec 2020 22:58:51

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:42:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '500'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	15 Dec 2020 22:58:51

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:42:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'mg (mg)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	15 Dec 2020 22:58:51

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:42:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered empty.	(b) (4) Ruba Zanaid (b) (4)	15 Dec 2020 22:58:51
	(b) (4)	

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:42:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'twice daily (BID)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	15 Dec 2020 22:58:51

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:42:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	15 Dec 2020 22:58:51

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:42:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Oral (ORAL)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	15 Dec 2020 22:58:51

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:42:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	15 Dec 2020 22:58:51

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:42:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '10 Dec 2020'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	15 Dec 2020 22:58:51

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:42:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '0'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	15 Dec 2020 22:58:51

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:42:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	30 Dec 2020 18:23:07
User entered 'Yes (Y)'	Ruba Zanaid (b) (4)	15 Dec 2020 22:58:51
	(b) (4)	

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:42:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '20 Dec 2020' reason for change: Data Entry Error	(b) (4)	30 Dec 2020 18:23:07
User entered empty.	Ruba Zanaid (b) (4)	15 Dec 2020 22:58:51
	(b) (4)	

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:42:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'No (N)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	15 Dec 2020 22:58:51

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:42:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:11
User entered '2'	System	15 Dec 2020 22:58:51

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:42:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:11
User entered '1'	System	15 Dec 2020 22:58:51

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:42:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:11
User entered '804 (804)'	System	15 Dec 2020 22:58:51

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:42:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:28
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	18 Dec 2020 02:14:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 02:14:49
Data point term sent to Coder	System	15 Dec 2020 23:00:46
User entered 'Metronidazole'	Ruba Zanaid (b) (4) (b) (4)	15 Dec 2020 22:59:57

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:42:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:28
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Yes (Y)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	15 Dec 2020 22:59:57

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:42:05

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:28
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Post appendectomy infection prophylaxis'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	15 Dec 2020 22:59:57

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:42:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:28
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '500'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	15 Dec 2020 22:59:57

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:42:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:28
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'mg (mg)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	15 Dec 2020 22:59:57

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:42:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:28
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	15 Dec 2020 22:59:57

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:42:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:28
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'three times daily (TID)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	15 Dec 2020 22:59:57

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:42:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:28
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	15 Dec 2020 22:59:57

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:42:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:28
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'Oral (ORAL)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	15 Dec 2020 22:59:57

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:42:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:28
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	15 Dec 2020 22:59:57

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:42:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:28
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '10 Dec 2020'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	15 Dec 2020 22:59:57

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:42:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:28
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '0'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	15 Dec 2020 22:59:57

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:42:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:28
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	30 Dec 2020 18:23:39
User entered 'Yes (Y)'	Ruba Zanaid (b) (4)	15 Dec 2020 22:59:57
	(b) (4)	

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:42:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:28
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered '20 Dec 2020' reason for change: Data Entry Error	(b) (4)	30 Dec 2020 18:23:39
User entered empty.	Ruba Zanaid (b) (4)	15 Dec 2020 22:59:57
	(b) (4)	

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:42:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:28
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 21:07:58
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 18:53:18
User entered 'No (N)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	15 Dec 2020 22:59:57

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:42:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:28
User entered '3'	System	15 Dec 2020 22:59:57

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:42:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:28
User entered '1'	System	15 Dec 2020 22:59:57

US3772187

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:42:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:48:28
User entered '804 (804)'	System	15 Dec 2020 22:59:57

US3772187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:42:05

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:47:23
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:12:03
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'Yes (Y)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 19:20:41

US3772187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:42:05

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:12:12
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered '7 Dec 2020'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 19:21:20

US3772187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:42:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:12:12
User closed query 'Per ETRTR, please consider updating AE page for Appendicitis event to check "Concomitant Procedure" box in Section "Other Action Taken".' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:32:08
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
Query 'Per ETRTR, please consider updating AE page for Appendicitis event to check "Concomitant Procedure" box in Section "Other Action Taken".' answered with 'Updated' (Site from CRA).	(b) (4) Emily Crews (b) (4)	05 Feb 2021 17:54:54
User opened query 'Per ETRTR, please consider updating AE page for Appendicitis event to check "Concomitant Procedure" box in Section "Other Action Taken".' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 20:15:20
User entered 'Appendectomy'	Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 19:21:20

US3772187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:42:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:12:12
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'Adverse Event (AE)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 19:21:20

US3772187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:42:05

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:12:12
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	08 Dec 2020 19:21:20

US3772187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:42:05

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:12:12
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered '07 Dec 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:46

US3772187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:42:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:12:12
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'Abscess Drainage'	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:46

US3772187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:42:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:12:12
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered 'Adverse Event (AE)'	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:46

US3772187

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:42:05

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:29
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:12:12
User signature succeeded.	Jamshid Saleh (b) (4)	24 Mar 2021 19:08:32
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	07 Jan 2021 17:51:46

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'USA-US107-2020-MRNA-1273-P301000008'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 15:26:19
Un-reviewed for Safety.	System	08 Dec 2020 18:43:24
User entered 'Yes (Y)'	System	08 Dec 2020 18:43:24
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 15:26:19
Un-reviewed for Safety.	System	08 Dec 2020 18:43:24
User entered 'Yes (Y)'	System	08 Dec 2020 18:43:24
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'Jamshid'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'Saleh'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered '3652 Eureka Way'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'Redding'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered '96001'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 15:26:19
User entered 'US'	System	08 Dec 2020 15:25:36

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Feb 2021 17:54:35
User entered '4'	System	25 Jan 2021 15:42:55
User entered '3'	System	16 Dec 2020 18:41:18
User entered '2'	System	09 Dec 2020 15:26:32
User entered '1'	System	08 Dec 2020 15:25:36

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'USA-US107-2020-MRNA-1273-P301000008'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 15:26:19
Un-reviewed for Safety.	System	08 Dec 2020 18:43:24
User entered 'Yes (Y)'	System	08 Dec 2020 18:43:24
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 15:26:19
Un-reviewed for Safety.	System	08 Dec 2020 18:43:24
User entered 'Yes (Y)'	System	08 Dec 2020 18:43:24
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'Jamshid'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'Saleh'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered '3652 Eureka Way'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'Redding'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered '96001'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 15:26:19
User entered 'US'	System	08 Dec 2020 15:25:36

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Feb 2021 17:54:35
User entered '4'	System	25 Jan 2021 15:42:55
User entered '3'	System	16 Dec 2020 18:41:18
User entered '2'	System	09 Dec 2020 15:26:32
User entered '1'	System	08 Dec 2020 15:25:36

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:42:05

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
User entered '08/Dec/2020 10:25'	System	08 Dec 2020 15:25:36

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:42:05

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)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 15:26:19
User entered '1'	(b) (4), (b) (6)	08 Dec 2020 15:25:36

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'USA-US107-2020-MRNA-1273-P301000008'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 15:26:19
Un-reviewed for Safety.	System	08 Dec 2020 18:43:24
User entered 'Yes (Y)'	System	08 Dec 2020 18:43:24
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 15:26:19
Un-reviewed for Safety.	System	08 Dec 2020 18:43:24
User entered 'Yes (Y)'	System	08 Dec 2020 18:43:24
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'Jamshid'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'Saleh'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered '3652 Eureka Way'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'Redding'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered '96001'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 15:26:19
User entered 'US'	System	08 Dec 2020 15:25:36

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Feb 2021 17:54:35
User entered '4'	System	25 Jan 2021 15:42:55
User entered '3'	System	16 Dec 2020 18:41:18
User entered '2'	System	09 Dec 2020 15:26:32
User entered '1'	System	08 Dec 2020 15:25:36

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:42:05

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
User entered '09/Dec/2020 15:26'	System	09 Dec 2020 15:26:32

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:42:05

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)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 18:40:57
User entered '1'	(b) (4), (b) (6)	09 Dec 2020 15:26:32

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'USA-US107-2020-MRNA-1273-P301000008'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 15:26:19
Un-reviewed for Safety.	System	08 Dec 2020 18:43:24
User entered 'Yes (Y)'	System	08 Dec 2020 18:43:24
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 15:26:19
Un-reviewed for Safety.	System	08 Dec 2020 18:43:24
User entered 'Yes (Y)'	System	08 Dec 2020 18:43:24
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'Jamshid'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'Saleh'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered '3652 Eureka Way'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'Redding'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered '96001'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 15:26:19
User entered 'US'	System	08 Dec 2020 15:25:36

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Feb 2021 17:54:35
User entered '4'	System	25 Jan 2021 15:42:55
User entered '3'	System	16 Dec 2020 18:41:18
User entered '2'	System	09 Dec 2020 15:26:32
User entered '1'	System	08 Dec 2020 15:25:36

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:42:05

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
User entered '16/Dec/2020 13:41'	System	16 Dec 2020 18:41:18

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:42:05

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)	23 Mar 2021 02:48:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:42:43
DataPoint Verified.	(b) (4), (b) (6)	20 Dec 2020 21:05:45
User entered '1'	(b) (4), (b) (6)	16 Dec 2020 18:41:18

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'USA-US107-2020-MRNA-1273-P301000008'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 15:26:19
Un-reviewed for Safety.	System	08 Dec 2020 18:43:24
User entered 'Yes (Y)'	System	08 Dec 2020 18:43:24
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 15:26:19
Un-reviewed for Safety.	System	08 Dec 2020 18:43:24
User entered 'Yes (Y)'	System	08 Dec 2020 18:43:24
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'Jamshid'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'Saleh'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered '3652 Eureka Way'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'Redding'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered '96001'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 15:26:19
User entered 'US'	System	08 Dec 2020 15:25:36

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Feb 2021 17:54:35
User entered '4'	System	25 Jan 2021 15:42:55
User entered '3'	System	16 Dec 2020 18:41:18
User entered '2'	System	09 Dec 2020 15:26:32
User entered '1'	System	08 Dec 2020 15:25:36

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:42:05

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:48:11
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
User entered '25/Jan/2021 10:42'	(b) (4) System	25 Jan 2021 15:42:55

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:42:05

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)	21 Apr 2021 06:48:11
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:50:31
User entered '1'	(b) (4), (b) (6)	25 Jan 2021 15:42:55

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'USA-US107-2020-MRNA-1273-P301000008'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 15:26:19
Un-reviewed for Safety.	System	08 Dec 2020 18:43:24
User entered 'Yes (Y)'	System	08 Dec 2020 18:43:24
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 15:26:19
Un-reviewed for Safety.	System	08 Dec 2020 18:43:24
User entered 'Yes (Y)'	System	08 Dec 2020 18:43:24
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'No (N)'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'Jamshid'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'Saleh'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered '3652 Eureka Way'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered 'Redding'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:24
User entered '96001'	System	08 Dec 2020 15:25:12

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Dec 2020 21:05:45
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 15:26:19
User entered 'US'	System	08 Dec 2020 15:25:36

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:42:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Feb 2021 17:54:35
User entered '4'	System	25 Jan 2021 15:42:55
User entered '3'	System	16 Dec 2020 18:41:18
User entered '2'	System	09 Dec 2020 15:26:32
User entered '1'	System	08 Dec 2020 15:25:36

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:42:05

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 06:48:11
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
User entered '08/Feb/2021 12:54'	(b) (4) System	08 Feb 2021 17:54:35

US3772187

Folder: SAE USA-US107-2020-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:42:05

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)	21 Apr 2021 06:48:11
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:56
Un-reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:54:35
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 17:54:35
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 17:50:31
User entered '0'	(b) (4), (b) (6)	08 Feb 2021 17:49:47