US3732207 (Prod: eStudySite - La Mesa - PPDS)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:21:23

All time stamps listed in this document are displayed in GMT

US3732207

Form: Participant Creation

Data signed: (b) (4) **25 Feb 2021 01:48:27**

Generated On: 12 Aug 2021 13:21:23

Participant ID	US3732207

mRNA-1273-P301 Completion Guidelines

US3732207

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 01:48:39

Generated On: 12 Aug 2021 13:21:23

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	27 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	SCRN

US3732207

Folder: Screening

Form: Demographics

Data signed: (b) (4) **25 Feb 2021 01:48:39**

Generated On: 12 Aug 2021 13:21:23

Date of Birth (MMM yyyy)	(b) (6) 1990
Age	30
Age Units	YEARS
Age (Derived)	30
Sex	Female ◯
	Male ⬤
Ethnicity	Hispanic or Latino ◯
	Not Hispanic or Latino ⬤
	Not Reported ◯
	Unknown ◯

Race (Check All That Apply)	
White	False
Black	False
Asian	True
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

US3732207

Folder: Screening

Form: Enrollment

Data signed: (b) (4) **25 Feb 2021 01:48:39**

Generated On: 12 Aug 2021 13:21:23

Date of Informed Consent *(dd MMM yyyy)*	27 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

US3732207

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) **25 Feb 2021 01:48:39**

Generated On: 12 Aug 2021 13:21:23

Did the participant meet all eligibility criteria?　　　　　　　Yes ⬤

　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ◯

US3732207

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) **25 Feb 2021 01:48:39**

Generated On: 12 Aug 2021 13:21:23

Were any significant conditions reported?   Yes ●

                                                             No ○

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) **25 Feb 2021 01:48:39**

Generated On: 12 Aug 2021 13:21:23

Condition	MIGRAINE HEADACHES
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

Condition	ANXIETY
Start date (dd MMM yyyy)	UN NOV 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

US3732207

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) **25 Feb 2021 01:48:39**

Generated On: 12 Aug 2021 13:21:23

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	27 AUG 2020
Time of assessment *(00:00-23:59)*	17:32 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 17:32
Height *(xxx.x)*	178.5 cm
Weight *(xxx.x)*	211.8 lb
BMI *(xxx.x)*	30.21529 kg/m^2
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)	

US3732207

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) **25 Feb 2021 01:48:39**

Generated On: 12 Aug 2021 13:21:23

Was the physical examination performed?   Yes ●

No ◯

Date of examination *(dd MMM yyyy)*   27 AUG 2020

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

US3732207

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 25 Feb 2021 01:48:39

Generated On: 12 Aug 2021 13:21:23

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

US3732207
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **25 Feb 2021 01:48:39**
Generated On: 12 Aug 2021 13:21:23

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	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	

US3732207
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **25 Feb 2021 01:48:39**
Generated On: 12 Aug 2021 13:21:23

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	27 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT1

US3732207

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) **25 Feb 2021 01:48:39**

Generated On: 12 Aug 2021 13:21:23

What was the date of randomization? *(dd MMM yyyy)*	27 AUG 2020
What was the participant's randomization number?	109418

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 ●

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) **25 Feb 2021 01:48:39**

Generated On: 12 Aug 2021 13:21:23

Height	ND - Not Done
Weight	ND - Not Done

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **25 Feb 2021 01:48:39**

Generated On: 12 Aug 2021 13:21:23

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	27 AUG 2020
Time of assessment *(00:00-23:59)*	17:32 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 17:32
Temperature *(xxx.x)*	98.1 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	56 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	79 mmHg
Diastolic Blood Pressure units	MMHG

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **25 Feb 2021 01:48:39**

Generated On: 12 Aug 2021 13:21:23

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	27 AUG 2020
Time of assessment *(00:00-23:59)*	18:44 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 18:44
Temperature *(xxx.x)*	97.5 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	53 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	73 mmHg
Diastolic Blood Pressure units	MMHG

US3732207

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) **25 Feb 2021 01:48:39**

Generated On: 12 Aug 2021 13:21:23

Was the physical examination performed? Yes ◯

No ⬤

Date of examination *(dd MMM yyyy)* _____

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

Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **25 Feb 2021 01:48:39**
Generated On: 12 Aug 2021 13:21:23

Was study treatment given?	Yes ⬤
	No ◯

If No, reason not given	
	Participant declined due to Adverse Event ◯
	Physician withheld dose due to Adverse Event ◯
	Death ◯
	Lost To Follow-Up ◯
	Physician Decision ◯
	Pregnancy ◯
	Protocol Deviation ◯
	Study Terminated by Sponsor ◯
	Withdrawal of Consent by Participant ◯
	Confirmed COVID-19 ◯
	Other ◯

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	27 AUG 2020
What was the treatment time? *(00:00-23:59)*	18:14 (24 HR)
Treatment Date and Time (derived)	27 AUG 2020 18:14
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

US3732207

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) **25 Feb 2021 01:48:39**

Generated On: 12 Aug 2021 13:21:23

Was the sample collected?	Yes ●
	No ○

Collection date *(dd MMM yyyy)*	27 AUG 2020
Collection time *(00:00-23:59)*	17:44 (24 HR)
Collection date and time (derived)	27 AUG 2020 17:44

US3732207

Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **25 Feb 2021 01:48:39**
Generated On: 12 Aug 2021 13:21:23

Collection date *(dd MMM yyyy)*			27 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:40	27 AUG 2020 17:40
Nasopharyngeal Swab 2	No		

US3732207

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) **25 Feb 2021 01:48:39**

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?   Yes ⬤

                                                                    No ◯

Continuing Flag   1

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	27 AUG 2020 18:41
PC Open Date & Time	27 AUG 2020 18:34
PC Close Date & Time	27 AUG 2020 21:04

FDA-CBER-2022-1614-3090374

US3732207
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.7 °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	28 AUG 2020 00:04
PC Open Date & Time	27 AUG 2020 21:59
PC Close Date & Time	28 AUG 2020 11:59

US3732207
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	97.5 °F

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

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

PC Time Stamp	28 AUG 2020 12:00
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	97.7 °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	29 AUG 2020 19:11
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3732207
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	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	30 AUG 2020 13:03
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3732207
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	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 19:13
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3732207
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 6

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

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

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

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

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

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

| Was **TEMPERATURE** taken? | Yes ● |
| | No ○ |

| Please record your **TEMPERATURE in °F** | 97.5 °F |

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

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

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

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	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	02 SEP 2020 12:38
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** 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	27 AUG 2020 18:37
PC Open Date & Time	27 AUG 2020 18:34
PC Close Date & Time	27 AUG 2020 21:04

FDA-CBER-2022-1614-3090382

US3732207
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	28 AUG 2020 00:05
PC Open Date & Time	27 AUG 2020 21:59
PC Close Date & Time	28 AUG 2020 11:59

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** 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	28 AUG 2020 12:00
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 3
Please record - **PAIN AT INJECTION SITE.** 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	29 AUG 2020 19:12
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3732207
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 4
Please record - **PAIN AT INJECTION SITE.** 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 AUG 2020 13:03
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 5
Please record - **PAIN AT INJECTION SITE.** 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 19:14
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 6
Please record - **PAIN AT INJECTION SITE.** 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 12:12
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 7
Please record - **PAIN AT INJECTION SITE.** 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 12:38
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
HEADACHE	None ⚪
	No interference with activity ⚫
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ⚪
	Any use of prescription pain reliever or prevents daily activity ⚪
FATIGUE	None ⚫
	No interference with activity ⚪
	Some interference with activity ⚪
	Significant; prevents daily activity ⚪
MUSCLE ACHES ALL OVER BODY	None ⚫
	No interference with activity ⚪
	Some interference with activity ⚪
	Significant; prevents daily activity ⚪
JOINT ACHES IN SEVERAL JOINTS	None ⚫
	No interference with activity ⚪
	Some interference with activity ⚪
	Significant; prevents daily activity ⚪
NAUSEA/VOMITING	None ⚫
	No interference with activity or 1-2 episodes/24 hours ⚪
	Some interference with activity or >2 episodes/24 hours ⚪
	Prevents daily activity, requires outpatient IV hydration ⚪
CHILLS	None ⚫
	No interference with activity ⚪
	Some interference with activity not requiring medical attention ⚪
	Prevents daily activity and requires medical attention ⚪

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤
	Yes ◯
PC Time stamp	27 AUG 2020 18:41
PC Open Date & Time	27 AUG 2020 18:34
PC Close Date & Time	27 AUG 2020 21:04

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

HEADACHE

None	⬤
No interference with activity	◯
Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity	◯
Any use of prescription pain reliever or prevents daily activity	◯

FATIGUE

None	⬤
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

MUSCLE ACHES ALL OVER BODY

None	⬤
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

JOINT ACHES IN SEVERAL JOINTS

None	⬤
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

NAUSEA/VOMITING

None	⬤
No interference with activity or 1-2 episodes/24 hours	◯
Some interference with activity or >2 episodes/24 hours	◯
Prevents daily activity, requires outpatient IV hydration	◯

CHILLS

None	⬤
No interference with activity	◯
Some interference with activity not requiring medical attention	◯
Prevents daily activity and requires medical attention	◯

FDA-CBER-2022-1614-3090392

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ● Yes ○
PC Time stamp	28 AUG 2020 00:05
PC Open Date & Time	27 AUG 2020 21:59
PC Close Date & Time	28 AUG 2020 11:59

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 2

HEADACHE

- None ⬤
- No interference with activity ◯
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ◯
- Any use of prescription pain reliever or prevents daily activity ◯

FATIGUE

- None ⬤
- No interference with activity ◯
- Some interference with activity ◯
- Significant; prevents daily activity ◯

MUSCLE ACHES ALL OVER BODY

- None ⬤
- No interference with activity ◯
- Some interference with activity ◯
- Significant; prevents daily activity ◯

JOINT ACHES IN SEVERAL JOINTS

- None ⬤
- No interference with activity ◯
- Some interference with activity ◯
- Significant; prevents daily activity ◯

NAUSEA/VOMITING

- None ⬤
- No interference with activity or 1-2 episodes/24 hours ◯
- Some interference with activity or >2 episodes/24 hours ◯
- Prevents daily activity, requires outpatient IV hydration ◯

CHILLS

- None ⬤
- No interference with activity ◯
- Some interference with activity not requiring medical attention ◯
- Prevents daily activity and requires medical attention ◯

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? — No ⬤

	Yes ◯
PC Time stamp	28 AUG 2020 12:00
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 3

HEADACHE

- None ●
- No interference with activity ○
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ○
- Any use of prescription pain reliever or prevents daily activity ○

FATIGUE

- None ○
- No interference with activity ○
- Some interference with activity ●
- Significant; prevents daily activity ○

MUSCLE ACHES ALL OVER BODY

- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

JOINT ACHES IN SEVERAL JOINTS

- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

NAUSEA/VOMITING

- None ●
- No interference with activity or 1-2 episodes/24 hours ○
- Some interference with activity or >2 episodes/24 hours ○
- Prevents daily activity, requires outpatient IV hydration ○

CHILLS

- None ●
- No interference with activity ○
- Some interference with activity not requiring medical attention ○
- Prevents daily activity and requires medical attention ○

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? — No ●

	Yes ◯
PC Time stamp	29 AUG 2020 19:13
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 4

HEADACHE
- None ●
- No interference with activity ○
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ○
- Any use of prescription pain reliever or prevents daily activity ○

FATIGUE
- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

MUSCLE ACHES ALL OVER BODY
- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

JOINT ACHES IN SEVERAL JOINTS
- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

NAUSEA/VOMITING
- None ●
- No interference with activity or 1-2 episodes/24 hours ○
- Some interference with activity or >2 episodes/24 hours ○
- Prevents daily activity, requires outpatient IV hydration ○

CHILLS
- None ●
- No interference with activity ○
- Some interference with activity not requiring medical attention ○
- Prevents daily activity and requires medical attention ○

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? — No ●

	Yes ◯
PC Time stamp	30 AUG 2020 13:04
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 5

HEADACHE

None	⚫
No interference with activity	◯
Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity	◯
Any use of prescription pain reliever or prevents daily activity	◯

FATIGUE

None	⚫
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

MUSCLE ACHES ALL OVER BODY

None	⚫
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

JOINT ACHES IN SEVERAL JOINTS

None	⚫
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

NAUSEA/VOMITING

None	⚫
No interference with activity or 1-2 episodes/24 hours	◯
Some interference with activity or >2 episodes/24 hours	◯
Prevents daily activity, requires outpatient IV hydration	◯

CHILLS

None	⚫
No interference with activity	◯
Some interference with activity not requiring medical attention	◯
Prevents daily activity and requires medical attention	◯

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⚫

	Yes ◯
PC Time stamp	31 AUG 2020 19:14
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 6

HEADACHE
- None ⬤
- No interference with activity ⬭
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ⬭
- Any use of prescription pain reliever or prevents daily activity ⬭

FATIGUE
- None ⬤
- No interference with activity ⬭
- Some interference with activity ⬭
- Significant; prevents daily activity ⬭

MUSCLE ACHES ALL OVER BODY
- None ⬤
- No interference with activity ⬭
- Some interference with activity ⬭
- Significant; prevents daily activity ⬭

JOINT ACHES IN SEVERAL JOINTS
- None ⬤
- No interference with activity ⬭
- Some interference with activity ⬭
- Significant; prevents daily activity ⬭

NAUSEA/VOMITING
- None ⬤
- No interference with activity or 1-2 episodes/24 hours ⬭
- Some interference with activity or >2 episodes/24 hours ⬭
- Prevents daily activity, requires outpatient IV hydration ⬭

CHILLS
- None ⬤
- No interference with activity ⬭
- Some interference with activity not requiring medical attention ⬭
- Prevents daily activity and requires medical attention ⬭

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? — No ⬤

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

	Yes ◯
PC Time stamp	01 SEP 2020 12:13
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 7

HEADACHE

None	●
No interference with activity	○
Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity	○
Any use of prescription pain reliever or prevents daily activity	○

FATIGUE

None	●
No interference with activity	○
Some interference with activity	○
Significant; prevents daily activity	○

MUSCLE ACHES ALL OVER BODY

None	●
No interference with activity	○
Some interference with activity	○
Significant; prevents daily activity	○

JOINT ACHES IN SEVERAL JOINTS

None	●
No interference with activity	○
Some interference with activity	○
Significant; prevents daily activity	○

NAUSEA/VOMITING

None	●
No interference with activity or 1-2 episodes/24 hours	○
Some interference with activity or >2 episodes/24 hours	○
Prevents daily activity, requires outpatient IV hydration	○

CHILLS

None	●
No interference with activity	○
Some interference with activity not requiring medical attention	○
Prevents daily activity and requires medical attention	○

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ●

	Yes ◯
PC Time stamp	02 SEP 2020 12:38
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3732207
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **25 Feb 2021 01:48:39**
Generated On: 12 Aug 2021 13:21:23

Was Contact Attempted?	Yes ⬤
	No ◯

Date of Contact or Contact Attempt *(dd MMM yyyy)*	03 SEP 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3732207

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) **25 Feb 2021 01:48:39**

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?　　　　　Yes ●

No ◯

Continuing Flag　　　　　1

US3732207
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **25 Feb 2021 01:48:39**
Generated On: 12 Aug 2021 13:21:23

| Was Contact Attempted? | Yes ● |
| | No ○ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 10 SEP 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3732207

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) **25 Feb 2021 01:48:39**

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?   Yes ●

                                                                      No ◯

Continuing Flag   1

US3732207
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **25 Feb 2021 01:48:39**
Generated On: 12 Aug 2021 13:21:23

| Was Contact Attempted? | Yes ● |
| | No ○ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 18 SEP 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3732207

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) **25 Feb 2021 01:48:39**

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?   Yes ●

                                                                                    No ○

Continuing Flag   1

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Apr 2021 21:05:06

Generated On: 12 Aug 2021 13:21:23

Timepoint	Pre-Dose ●
	Post-Dose ○
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	

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **09 Apr 2021 21:05:06**

Generated On: 12 Aug 2021 13:21:23

Timepoint	Pre-Dose ⭕
	Post-Dose 🔘
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 _____

US3732207

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) **09 Apr 2021 21:05:06**

Generated On: 12 Aug 2021 13:21:23

Was the physical examination performed?   Yes ◯

No ⬤

Date of examination *(dd MMM yyyy)*   _____

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

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   SUBJECT DID NOT QUALIFY
Participant, Protocol Deviation, or Other, specify   FOR SECOND INJECTION DUE
                                                                   TO AE SYMPTOMATIC COVID

What was the study treatment?   _____

What was the treatment date? *(dd MMM yyyy)*   _____

What was the treatment time? *(00:00-23:59)*   _____

Treatment Date and Time (derived)   _____

Which arm was used to give treatment?   Left Arm ◯

                                                                   Right Arm ◯

What was the frequency of the study treatment dosing?   _____

What was the route of administration for the study treatment? _____

US3732207

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **09 Apr 2021 21:05:06**

Generated On: 12 Aug 2021 13:21:23

Was the sample collected?   Yes ◯

No ⬤

Collection date *(dd MMM yyyy)*

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

Collection date and time (derived)

US3732207

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **09 Apr 2021 21:05:06**

Generated On: 12 Aug 2021 13:21:23

Collection date *(dd MMM yyyy)*

Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	No		

US3732207
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **25 Feb 2021 01:48:39**
Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?   Yes ◯

                                                                    No ⬤

Continuing Flag

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:21:23

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) **25 Feb 2021 01:48:27**

Generated On: 12 Aug 2021 13:21:23

Date of Contact	18 SEP 2020
Time of Contact	10:21
Date and Time of Contact (derived)	18 SEP 2020 10:21
Type of Contact	Clinic Visit - Scheduled ⚪
	Clinical Visit - Unscheduled ⚪
	Safety Call ⬤
	Convalescent Tele-visit ⚪
Has the subject reported symptoms of SARS-COV-2?	Yes ⬤
	No ⚪

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) **28 Apr 2021 22:21:44**

Generated On: 12 Aug 2021 13:21:23

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 ⬭

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	19 SEP 2020
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	99.0 F
Chills	None ◯
	Mild ◯
	Moderate ●
	Severe ◯
	Not Done ◯
Cough	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ●
	Mild ◯
	Moderate ◯
	Severe ◯

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 ⭕

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 ○

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (2)
Data signed: (b) (4) **28 Apr 2021 22:21:44**
Generated On: 12 Aug 2021 13:21:23

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	○

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯

Date	20 SEP 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	

Chills	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Cough	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Shortness of Breath	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯

Difficulty Breathing	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) **28 Apr 2021 22:21:44**

Generated On: 12 Aug 2021 13:21:23

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 ◯

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 ◯

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (3)
Data signed: (b) (4) **28 Apr 2021 22:21:44**
Generated On: 12 Aug 2021 13:21:23

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 ○

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (3)
Data signed: (b) (4) **28 Apr 2021 22:21:44**
Generated On: 12 Aug 2021 13:21:23

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	21 SEP 2020
Assessment Not Done	False
O2 Saturation	96 %
O2 Saturation Units	%
Temperature	101.0 F
Chills	None ◯
	Mild ◯
	Moderate ◯
	Severe ●
	Not Done ◯
Cough	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ◯
	Mild ◯
	Moderate ●
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ◯
	Mild ◯
	Moderate ●
	Severe ◯

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 ◯

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 ⦰

FDA-CBER-2022-1614-3090432

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (4)
Data signed: (b) (4) **28 Apr 2021 22:21:44**
Generated On: 12 Aug 2021 13:21:23

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 ○

	Day 33 ⬭
	Day 34 ⬭
	Day 35 ⬭
	Day 36 ⬭
	Day 37 ⬭
	Day 38 ⬭
	Day 39 ⬭
	Day 40 ⬭
Date	22 SEP 2020
Assessment Not Done	False
O2 Saturation	96 %
O2 Saturation Units	%
Temperature	99.0 F
Chills	None ⬭
	Mild ⬭
	Moderate ⬭
	Severe ⬤
	Not Done ⬭
Cough	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Shortness of Breath	None ⬭
	Mild ⬤
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Difficulty Breathing	None ⬭
	Mild ⬤
	Moderate ⬭
	Severe ⬭

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 ◯

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

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (5)
Data signed: (b) (4) **28 Apr 2021 22:21:44**
Generated On: 12 Aug 2021 13:21:23

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 ◯

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) **28 Apr 2021 22:21:44**

Generated On: 12 Aug 2021 13:21:23

	Day 33 ⭕
	Day 34 ⭕
	Day 35 ⭕
	Day 36 ⭕
	Day 37 ⭕
	Day 38 ⭕
	Day 39 ⭕
	Day 40 ⭕
Date	18 SEP 2020
Assessment Not Done	False
O2 Saturation	96 %
O2 Saturation Units	%
Temperature	97.5 F
Chills	None ⭕
	Mild ⭕
	Moderate ⬤
	Severe ⭕
	Not Done ⭕
Cough	None ⬤
	Mild ⭕
	Moderate ⭕
	Severe ⭕
	Not Done ⭕
Shortness of Breath	None ⬤
	Mild ⭕
	Moderate ⭕
	Severe ⭕
	Not Done ⭕
Difficulty Breathing	None ⬤
	Mild ⭕
	Moderate ⭕
	Severe ⭕

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 ◯

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 ○

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) **28 Apr 2021 22:21:44**

Generated On: 12 Aug 2021 13:21:23

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	◯

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯

Date	23 SEP 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ◯
	Mild ◯
	Moderate ◯
	Severe ◯

FDA-CBER-2022-1614-3090442

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 ⬭

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 ⬭

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (16)
Data signed: (b) (4) **28 Apr 2021 22:21:44**
Generated On: 12 Aug 2021 13:21:23

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 ◯

	Day 33 ⭕
	Day 34 ⭕
	Day 35 ⭕
	Day 36 ⭕
	Day 37 ⭕
	Day 38 ⭕
	Day 39 ⭕
	Day 40 ⭕
Date	15 SEP 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	99.0 F
Chills	None ⭕
	Mild ⭕
	Moderate ⬤
	Severe ⭕
	Not Done ⭕
Cough	None ⬤
	Mild ⭕
	Moderate ⭕
	Severe ⭕
	Not Done ⭕
Shortness of Breath	None ⬤
	Mild ⭕
	Moderate ⭕
	Severe ⭕
	Not Done ⭕
Difficulty Breathing	None ⬤
	Mild ⭕
	Moderate ⭕
	Severe ⭕

	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	○

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 ○

US3732207

Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (17)
Data signed: (b) (4) 28 Apr 2021 22:21:44
Generated On: 12 Aug 2021 13:21:23

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 ◯

	Day 33 ⬭
	Day 34 ⬭
	Day 35 ⬭
	Day 36 ⬭
	Day 37 ⬭
	Day 38 ⬭
	Day 39 ⬭
	Day 40 ⬭
Date	16 SEP 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	99.0 F
Chills	None ⬭
	Mild ⬭
	Moderate ⬤
	Severe ⬭
	Not Done ⬭
Cough	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Shortness of Breath	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Difficulty Breathing	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭

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 ◯

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 ○

FDA-CBER-2022-1614-3090452

US3732207

Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (18)
Data signed: (b) (4) **28 Apr 2021 22:21:44**
Generated On: 12 Aug 2021 13:21:23

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	◯

	Day 33 ○
	Day 34 ○
	Day 35 ○
	Day 36 ○
	Day 37 ○
	Day 38 ○
	Day 39 ○
	Day 40 ○

Date	17 SEP 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	99.0 F

Chills	None ○
	Mild ○
	Moderate ●
	Severe ○
	Not Done ○

Cough	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○

Shortness of Breath	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○

Difficulty Breathing	None ●
	Mild ○
	Moderate ○
	Severe ○

FDA-CBER-2022-1614-3090454

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 ◯

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) **28 Apr 2021 22:21:44**

Generated On: 12 Aug 2021 13:21:23

Nasal Congestion

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Runny Nose (Rhinorrhea)

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Nausea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Vomiting

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Diarrhea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Sore Throat

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Data signed: (b) (4) **28 Apr 2021 22:21:44**

Generated On: 12 Aug 2021 13:21:23

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 ○

	Day 33 ⬭
	Day 34 ⬭
	Day 35 ⬭
	Day 36 ⬭
	Day 37 ⬭
	Day 38 ⬭
	Day 39 ⬭
	Day 40 ⬭
Date	14 SEP 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	99.0 F
Chills	None ⬭
	Mild ⬭
	Moderate ●
	Severe ⬭
	Not Done ⬭
Cough	None ●
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Shortness of Breath	None ●
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Difficulty Breathing	None ●
	Mild ⬭
	Moderate ⬭
	Severe ⬭

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 ◯

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 ○

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4)   **25 Feb 2021 01:48:27**

Generated On: 12 Aug 2021 13:21:23

Date of Visit	18 SEP 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	18 SEP 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)	1

Did the subject have Respiratory Rates ≥ 30 per Minute?   Yes ○   No ●

If Yes, provide:

  Start Date _____

  End Date _____

  Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute   Yes ○   No ●

If Yes, provide:

  Start Date _____

  End Date _____

  Heart Rate _____

Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?   Yes ○   No ●

If Yes, provide:

  Start Date _____

  End Date _____

  Oxygen Saturation _____

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?   Yes ○   No ●

If Yes, provide:

  Start Date _____

  End Date _____

  PaO2 _____

Did the subject have Respiratory failure?   Yes ○   No ●

  Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?   Yes ○   No ●

  Start Date _____

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

Ventilator Support:

High-Flow Oxygen?   Yes ◯
                                                                   No ◯

   Start Date _____

   End Date _____

Non-Invasive Ventilation?   Yes ◯
                                                                   No ◯

   Start Date _____

   End Date _____

 Mechanical Ventilation?   Yes ◯
                                                                   No ◯

   Start Date _____

   End Date _____

ECMO?   Yes ◯
                                                                   No ◯

   Start Date _____

   End Date _____

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60   Yes ◯
mmHg   No ⬤

   Start Date _____

   End Date _____

Evidence of Shock Requires   Yes ◯
Vasopressors   No ◯

   Start Date _____

   End Date _____

Acute Renal Dysfunction?   Yes ◯
                                                                   No ◯

   Start Date _____

FDA-CBER-2022-1614-3090463

Hepatic Dysfunction?   Yes ◯
                                                            No ◯

Start Date   _____

Neurologic Dysfunction?   Yes ◯
                                                            No ◯

Start Date   _____

Evidence of Pneumonia:

Clinical Evidence   Yes ◯
                                                            No ⬤

Date of Assessment   _____

Radiographical Evidence   Yes ◯
                                                            No ◯

Date of Assessment   _____

Admission to an intensive care unit due to SARS-CoV-2   Yes ◯
                                                            No ⬤

Start Date   _____
End Date   _____

FDA-CBER-2022-1614-3090464

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) **25 Feb 2021 01:48:27**

Generated On: 12 Aug 2021 13:21:23

Generate Next COVID-19 Assessment   Yes ◯

                                                                  No ⬤

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) **25 Feb 2021 01:48:39**

Generated On: 12 Aug 2021 13:21:23

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	20 SEP 2020
Day 5	No	
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

US3732207

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) **25 Feb 2021 01:48:39**

Generated On: 12 Aug 2021 13:21:23

Was this visit performed?	Yes ⬤
	No ◯
Visit date (dd MMM yyyy)	18 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤
Folder OID	SICKD1

US3732207
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Data signed: (b) (4) **25 Feb 2021 01:48:39**
Generated On: 12 Aug 2021 13:21:23

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	18 SEP 2020
Time of assessment *(00:00-23:59)*	13:19 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 13:19
Height *(xxx.x)*	178.5 cm
Weight *(xxx.x)*	211.9 lb
Temperature *(xxx.x)*	97.5 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	63 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732207

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) **25 Feb 2021 01:48:39**

Generated On: 12 Aug 2021 13:21:23

Was the physical examination performed? Yes ●

No ○

Date of examination *(dd MMM yyyy)* 18 SEP 2020

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

US3732207

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) **25 Feb 2021 01:48:39**

Generated On: 12 Aug 2021 13:21:23

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ●
	No ◯
	NA (COVID-19 Negative) ◯

| Date of Collection | 18 SEP 2020 |

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) **25 Feb 2021 01:48:27**

Generated On: 12 Aug 2021 13:21:23

Was this visit performed?	Yes ◯
	No ⬤

Visit date (dd MMM yyyy) _____

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

Folder OID   SICKD28

US3732207
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Data signed: (b) (4) **25 Feb 2021 01:48:27**
Generated On: 12 Aug 2021 13:21:23

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)

Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Data signed: (b) (4)   **25 Feb 2021 01:48:27**
Generated On: 12 Aug 2021 13:21:23

Was the physical examination performed?   Yes ◯

                                                                               No ⬤

Date of examination *(dd MMM yyyy)*   _____

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

US3732207

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) **25 Feb 2021 01:48:27**

Generated On: 12 Aug 2021 13:21:23

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ◯
	No ⬤
	NA (COVID-19 Negative) ◯

Date of Collection

US3732207

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

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

Was this visit performed?	Yes ◯
	No ◯

Visit date (dd MMM yyyy)	

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

Folder OID	

US3732207

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

Form: Unblinding

Generated On: 12 Aug 2021 13:21:23

Date of updated informed consent *(dd MMM yyyy)*	
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	

| Was the participant unblinded? | Yes ◯ |
| | No ◯ |

| Under what version of the Protocol was the Participant unblinded? | Amendment 5 ◯ |
| | Amendment 6 or later ◯ |

| Date of unblinding *(dd MMM yyyy)* | |

| Participant randomization assignment | mRNA-1273 ◯ |
| | Placebo ◯ |

Actual Dose 1	mRNA-1273 ◯
	Placebo ◯
	Not Administered ◯

Actual Dose 2	mRNA-1273 ◯
	Placebo ◯
	Not Administered ◯

| Will participant receive mRNA-1273? | Yes ◯ |
| | No ◯ |

| Placebo Only Flag | |
| Continuing with mRNA-1273 | |

Was the sample collected?	Yes	◯
	No	◯

Collection date *(dd MMM yyyy)*	
Collection time *(00:00-23:59)*	
Collection date and time (derived)	

Was the sample collected? Yes ◯

No ◯

Collection date *(dd MMM yyyy)*

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

Collection Date and Time (derived)

US3732207

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **25 Feb 2021 01:48:27**

Generated On: 12 Aug 2021 13:21:23

Did the participant experience any adverse events?   Yes ⬤

No ◯

If Yes, enter details on the Adverse Events form.

AEID	USA-US102-2020-MRNA-1273-P30 1000002
Adverse event	SYMPTOMATIC COVID-19

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)*	14 SEP 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing?   Yes ●   No ○

If not Ongoing, end date *(dd MMM yyyy)*	
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 ○

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **25 Feb 2021 01:48:27**

Generated On: 12 Aug 2021 13:21:23

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	
Not Related	●
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	True
Concomitant Procedure	False

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

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **25 Feb 2021 01:48:27**

Generated On: 12 Aug 2021 13:21:23

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

No ◯

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

Name of Medication	AIMAVIG

Prophylaxis	Yes ◯
	No ⬤

Indication	MIGRAINE HEADACHES

Dose per administration	70

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 ◯

FDA-CBER-2022-1614-3090483

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2008
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
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 ◯

Name of Medication	ATIVAN

Prophylaxis	Yes ◯
	No ⬤

Indication	ANXIETY

Dose per administration	1

Dose unit	mg ⬤
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ◯

If dose unit is Other, specify	

Frequency	once daily ◯
	twice daily ◯
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ⬤
	once ◯
	unknown ◯
	other ◯

If frequency is Other, specify	

Route of administration	Oral ⬤
	Topical ◯
	Subcutaneous ◯
	Transdermal ◯
	Intraocular ◯

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2010
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
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 ◯

FDA-CBER-2022-1614-3090486

Name of Medication — ADVIL

Prophylaxis
- Yes ◯
- No ⬤

Indication — SYMPTOMATIC COVID-19

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 — EVERY 6 HOURS

Route of administration
- Oral ⬤
- Topical ◯
- Subcutaneous ◯
- Transdermal ◯
- Intraocular ◯

FDA-CBER-2022-1614-3090487

	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ◯
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	15 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
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 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) **25 Feb 2021 01:48:27**

Generated On: 12 Aug 2021 13:21:23

Name of Medication	ACETAMINOPHEN

Prophylaxis	Yes ⚪
	No ⚫

Indication	SYMPTOMATIC COVID-19
Dose per administration	1000

Dose unit	mg ⚫
	ug ⚪
	mL ⚪
	g ⚪
	IU ⚪
	tablet ⚪
	capsule ⚪
	puff ⚪
	Other ⚪

If dose unit is Other, specify	

Frequency	once daily ⚪
	twice daily ⚪
	three times daily ⚪
	four times daily ⚪
	every other day ⚪
	every week ⚪
	every month ⚪
	as needed ⚪
	once ⚪
	unknown ⚪
	other ⚫

If frequency is Other, specify	EVERY 6 HOURS

Route of administration	Oral ⚫
	Topical ⚪
	Subcutaneous ⚪
	Transdermal ⚪
	Intraocular ⚪

PRODUCTION RELEASE (v12.003
EAB) (1725)

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) **25 Feb 2021 01:48:27**

Generated On: 12 Aug 2021 13:21:23

	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ◯
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	17 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
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 ◯

US3732207

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) **25 Feb 2021 01:48:27**

Generated On: 12 Aug 2021 13:21:23

Were any concomitant procedures performed?   Yes ⃝

                                                      No ●

If yes, please complete Concomitant Procedures form.

US3732207

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) **25 Feb 2021 01:48:39**

Generated On: 12 Aug 2021 13:21:23

Date of dosing discontinuation (dd MMM yyyy)	21 SEP 2020

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

_____

Date of study discontinuation/completion *(dd MMM yyyy)*	24 SEP 2020

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	SUBJECT NO LONGER WANTS TO PARTICIPATE DUE TO TOO MANY FOLLOW-UP CALLS/VISITS (SINCE THEY ARE CONFIRMED COVID POSITIVE)

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 ◯

FDA-CBER-2022-1614-3090493

SAEID	USA-US102-2020-MRNA-1273-P30 1000002
Serious	Yes ◯ No ⬤
Death	Yes ◯ No ⬤
Life threatening	Yes ◯ No ⬤
Requires inpatient or prolongation of existing Hospitalization	Yes ◯ No ⬤
Persistent or significant disability or incapacity	Yes ◯ No ⬤
Congenital anomaly or birth defect	Yes ◯ No ⬤
Other medically important event	Yes ◯ No ⬤
Investigator's First Name	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

SAEID	USA-US102-2020-MRNA-1273-P30 1000002
Serious	Yes ⚪ No ⬤
Death	Yes ⚪ No ⬤
Life threatening	Yes ⚪ No ⬤
Requires inpatient or prolongation of existing Hospitalization	Yes ⚪ No ⬤
Persistent or significant disability or incapacity	Yes ⚪ No ⬤
Congenital anomaly or birth defect	Yes ⚪ No ⬤
Other medically important event	Yes ⚪ No ⬤
Investigator's First Name	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	23/SEP/2020 12:11
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

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) **26 Feb 2021 01:55:45**

Generated On: 12 Aug 2021 13:21:23

SAEID	USA-US102-2020-MRNA-1273-P30 1000002
Serious	Yes ◯ No ⬤
Death	Yes ◯ No ⬤
Life threatening	Yes ◯ No ⬤
Requires inpatient or prolongation of existing Hospitalization	Yes ◯ No ⬤
Persistent or significant disability or incapacity	Yes ◯ No ⬤
Congenital anomaly or birth defect	Yes ◯ No ⬤
Other medically important event	Yes ◯ No ⬤
Investigator's First Name	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	08/OCT/2020 13:47
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

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) **26 Feb 2021 01:55:45**

Generated On: 12 Aug 2021 13:21:23

SAEID	USA-US102-2020-MRNA-1273-P30 1000002
Serious	Yes ◯ No ⬤
Death	Yes ◯ No ⬤
Life threatening	Yes ◯ No ⬤
Requires inpatient or prolongation of existing Hospitalization	Yes ◯ No ⬤
Persistent or significant disability or incapacity	Yes ◯ No ⬤
Congenital anomaly or birth defect	Yes ◯ No ⬤
Other medically important event	Yes ◯ No ⬤
Investigator's First Name	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	25/FEB/2021 15:43
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

℔

US3732207

Form: Participant Creation

Generated On: 12 Aug 2021 13:21:23

Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 21:57:05
User entered 'US3732207'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 00:34:34

US3732207
Form: Participant Creation
Generated On: 12 Aug 2021 13:21:23

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57

US3732207

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 21:57:18
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:50:08

US3732207
Folder: Screening
Form: Visit Date
Generated On: 12 Aug 2021 13:21:23

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 21:57:18
User entered '27 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 00:34:35

US3732207

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:57:18
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:50:08

US3732207
Folder: Screening
Form: Visit Date
Generated On: 12 Aug 2021 13:21:23
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User entered 'SCRN'	System	01 Sep 2020 00:50:08

US3732207

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 21:58:16
User entered (b) (6) 1990'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 00:34:37

US3732207
Folder: Screening
Form: Demographics
Generated On: 12 Aug 2021 13:21:23
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:16
User entered '30'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:06

US3732207

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User entered 'YEARS'	System	01 Sep 2020 00:51:06

US3732207

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User entered '30'	System	28 Aug 2020 01:15:29

US3732207

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:16
User entered 'Male (M)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:06

US3732207
Folder: Screening
Form: Demographics
Generated On: 12 Aug 2021 13:21:23
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 21:58:16
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:06

US3732207

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 21:58:16
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:06

US3732207
Folder: Screening
Form: Demographics
Generated On: 12 Aug 2021 13:21:23
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:16
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:06

US3732207

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 21:58:16
User entered '1'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:06

US3732207

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 21:58:16
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:06

US3732207

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 21:58:16
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:06

US3732207

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:16
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:06

US3732207

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:16
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:06

FDA-CBER-2022-1614-3090517

US3732207

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:16
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:06

US3732207

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:16
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:06

US3732207

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:21:23

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:34
User entered '27 Aug 2020'	Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 01:15:29

US3732207

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:21:23

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User entered 'Aug 2020'	System	28 Aug 2020 01:15:29

US3732207

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:21:23

Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User entered '2020'	System	28 Aug 2020 01:15:29

US3732207

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:21:23

Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:34
User entered 'Amendment 3 (3)'	Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 01:15:29

US3732207
Folder: Screening
Form: Enrollment
Generated On: 12 Aug 2021 13:21:23

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:34
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 01:15:29

US3732207

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:21:23

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:34
User entered empty.	Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 01:15:29

Folder: Screening
Form: Enrollment
Generated On: 12 Aug 2021 13:21:23
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:34
User entered empty.	Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 01:15:29

US3732207
Folder: Screening
Form: Enrollment
Generated On: 12 Aug 2021 13:21:23
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 21:58:34
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 01:15:29

US3732207

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:21:23

If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 21:58:34
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 00:34:35

US3732207

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:21:23

Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User entered '1'	System	28 Aug 2020 01:15:33

US3732207

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:21:23

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:42
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 01:15:33

US3732207

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:21:23

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:58:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:29

US3732207

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:21:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:59:31
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 00:53:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 00:53:39
Data point term sent to Coder	System	01 Sep 2020 00:52:38
User entered 'migraine headaches'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:43

US3732207

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:21:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:59:31
User entered 'un UNK 2008'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:43

US3732207

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:21:23

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:59:31
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:43

US3732207

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:21:23

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:59:31
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:43

Folder: Screening
Form: Medical History (1)
Generated On: 12 Aug 2021 13:21:23
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:59:31
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:43

US3732207

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:21:23

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:59:31
User entered '0'	Lauren Arnett (b) (4)	01 Sep 2020 00:51:43

US3732207

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:21:23

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User entered 'Jan 2008'	System	01 Sep 2020 00:51:43

US3732207

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:21:23

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User entered '2008'	System	01 Sep 2020 00:51:43

US3732207

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:21:23

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User entered empty.	System	01 Sep 2020 00:51:43

US3732207

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:21:23

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User entered empty.	System	01 Sep 2020 00:51:43

US3732207

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:21:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:59:31
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 00:53:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 00:53:39
Data point term sent to Coder	System	01 Sep 2020 00:52:38
User entered 'anxiety'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:53

US3732207

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:21:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:59:31
User entered 'un Nov 2010'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:53

US3732207

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:21:23

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:59:31
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:53

US3732207

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:21:23

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:59:31
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:53

US3732207

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:59:31
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:53

US3732207

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:21:23

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 21:59:31
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:51:53

US3732207

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:21:23

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User entered 'Nov 2010'	System	01 Sep 2020 00:51:53

US3732207

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:21:23

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User entered '2010'	System	01 Sep 2020 00:51:53

US3732207

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:21:23

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User entered empty.	System	01 Sep 2020 00:51:53

US3732207

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:21:23

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User entered empty.	System	01 Sep 2020 00:51:53

US3732207

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:04:21
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	01 Sep 2020 00:54:07

US3732207
Folder: Screening
Form: Vital Signs
Generated On: 12 Aug 2021 13:21:23
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:04:21
User entered '27 Aug 2020'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:07

US3732207

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:04:21
User entered '17:32'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:07

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User entered '27 Aug 2020 17:32'	System	01 Sep 2020 00:54:07

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:04:21
User entered '178.5' cm	Lauren Arnett (b) (4)	01 Sep 2020 00:54:07
DataPoint set to visible.	(b) (4) System	28 Aug 2020 01:15:33

US3732207
Folder: Screening
Form: Vital Signs
Generated On: 12 Aug 2021 13:21:23

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:04:21
User entered '211.8' lb	Lauren Arnett (b) (4)	01 Sep 2020 00:54:07
DataPoint set to visible.	System	28 Aug 2020 01:15:33

US3732207

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User entered '30.21529'	System	01 Sep 2020 00:54:07
DataPoint set to visible.	System	28 Aug 2020 01:15:33

US3732207

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User entered 'kg/m2'	System	01 Sep 2020 00:54:07
DataPoint set to visible.	System	28 Aug 2020 01:15:33

US3732207
Folder: Screening
Form: Vital Signs
Generated On: 12 Aug 2021 13:21:23
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:04:21
User entered missing code ND - Not Done.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:07

US3732207

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:04:21
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:07

US3732207
Folder: Screening
Form: Vital Signs
Generated On: 12 Aug 2021 13:21:23
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:04:21
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:07

US3732207

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:04:21
User entered missing code ND - Not Done.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:07

US3732207
Folder: Screening
Form: Vital Signs
Generated On: 12 Aug 2021 13:21:23
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User entered 'bpm'	System	01 Sep 2020 00:54:07

US3732207
Folder: Screening
Form: Vital Signs
Generated On: 12 Aug 2021 13:21:23
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:04:21
User entered missing code ND - Not Done.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:07

US3732207

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User entered 'breaths/min'	System	01 Sep 2020 00:54:07

US3732207

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:04:21
User entered missing code ND - Not Done.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:07

US3732207

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User entered 'mmHg'	System	01 Sep 2020 00:54:07

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:04:21
User entered missing code ND - Not Done.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User entered 'mmHg'	System	01 Sep 2020 00:54:07

US3732207

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59

US3732207
Folder: Screening
Form: Vital Signs
Generated On: 12 Aug 2021 13:21:23

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59

US3732207

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:04:34
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	01 Sep 2020 00:54:17
	(b) (4)	

US3732207

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:04:34
User entered '27 Aug 2020'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:17

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207
Folder: Screening
Form: Risk of Exposure
Generated On: 12 Aug 2021 13:21:23
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207
Folder: Screening
Form: Risk of Exposure
Generated On: 12 Aug 2021 13:21:23
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207
Folder: Screening
Form: Risk of Exposure
Generated On: 12 Aug 2021 13:21:23
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered '1'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207
Folder: Screening
Form: Risk of Exposure
Generated On: 12 Aug 2021 13:21:23
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:01
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:54:40

US3732207
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 12 Aug 2021 13:21:23
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:33
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:30
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:55:00

US3732207
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 12 Aug 2021 13:21:23
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:33
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:30
User entered '27 Aug 2020'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:55:00

US3732207
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:33
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:30
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:55:00

US3732207
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 12 Aug 2021 13:21:23
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:33
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered 'VISIT1'	System	01 Sep 2020 00:55:00

US3732207

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:39
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:45
User entered '27 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 00:39:29

Folder: Visit 1 Day 1
Form: Randomization
Generated On: 12 Aug 2021 13:21:23

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:39
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:45
User entered '109418'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 00:39:29

US3732207
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 12 Aug 2021 13:21:23

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:39
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:05:45
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 00:39:29

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)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:39
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:45
User closed query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:07:14
Query 'PER CDM: Please complete this section of the form.' answered with 'complete ' (Site from DM).	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 21:49:26
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 21:48:58
User opened query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 09:38:28

US3732207

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:21:23

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:39
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:45
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 21:48:58

US3732207

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:39
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:45
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 21:48:58

US3732207
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 12 Aug 2021 13:21:23

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:39
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:45
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 21:48:58

US3732207

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:21:23

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:39
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:05:45
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 21:48:58

FDA-CBER-2022-1614-3090607

US3732207
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 12 Aug 2021 13:21:23

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:39
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:42:30
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).		01 Dec 2020 03:52:28
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'updated per source ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 17:56:11
User entered 'No (N)'	(b) (4), (b) (6)	24 Nov 2020 17:55:52
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 20:47:09
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:22:43
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:22:42

US3732207
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 12 Aug 2021 13:21:23
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:08:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:49:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 12 Aug 2021 13:21:23
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:08:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:49:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 12 Aug 2021 13:21:23
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:08:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:49:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 12 Aug 2021 13:21:23
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:08:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:49:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User accepted default value 'Pre-Dose (PREDOSE)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered '27 Aug 2020'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered '17:32'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered '27 Aug 2020 17:32'	System	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered '98.1' F	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered 'Oral (Oral)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 12 Aug 2021 13:21:23
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 12 Aug 2021 13:21:23

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered '56'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered 'bpm'	System	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered '16'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered 'breaths/min'	System	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered '106'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered 'mmHg'	System	01 Sep 2020 00:57:09

Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered '79'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

FDA-CBER-2022-1614-3090627

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered 'mmHg'	System	01 Sep 2020 00:57:09

US3732207
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 12 Aug 2021 13:21:23
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:08:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:49:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:08:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:49:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User accepted default value 'Post-Dose (POSTDOSE)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

FDA-CBER-2022-1614-3090631

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered '27 Aug 2020'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered '18:44'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 12 Aug 2021 13:21:23

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered '27 Aug 2020 18:44'	System	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered '97.5' F	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered 'Oral (Oral)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

FDA-CBER-2022-1614-3090637

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered '53'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered 'bpm'	System	01 Sep 2020 00:57:09

US3732207
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 12 Aug 2021 13:21:23
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered '17'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered 'breaths/min'	System	01 Sep 2020 00:57:09

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered '126'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered 'mmHg'	System	01 Sep 2020 00:57:09

FDA-CBER-2022-1614-3090644

US3732207

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:09:09
User entered '73'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered 'mmHg'	System	01 Sep 2020 00:57:09

FDA-CBER-2022-1614-3090646

US3732207
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 12 Aug 2021 13:21:23
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:55
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:10:43
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:14

US3732207

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:41:55
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:10:43
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:14

US3732207
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 12 Aug 2021 13:21:23
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:42:01
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:11:02
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 01:15:51

US3732207
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 12 Aug 2021 13:21:23
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:42:01
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:11:02
User entered empty.	Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 01:15:51

US3732207
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:42:01
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:11:02
User entered empty.	Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 01:15:51

US3732207
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 12 Aug 2021 13:21:23
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:42:01
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 01:15:51

Folder: Visit 1 Day 1
Form: Exposure
Generated On: 12 Aug 2021 13:21:23

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:42:01
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:11:02
User entered '27 Aug 2020'	Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 01:15:51

US3732207

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:42:01
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:11:02
User entered '18:14'	Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 01:15:51

US3732207

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:42:01
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered '27 Aug 2020 18:14'	System	28 Aug 2020 01:15:51

US3732207
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 12 Aug 2021 13:21:23
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:42:01
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:11:02
User entered 'Left Arm (LEFT ARM)'	Lauren Arnett (b) (4) (b) (4)	28 Aug 2020 01:15:51

Folder: Visit 1 Day 1
Form: Exposure
Generated On: 12 Aug 2021 13:21:23

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:42:01
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:11:02
User entered 'ONCE'	System	28 Aug 2020 01:15:51

US3732207

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:42:01
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 01:15:51

US3732207

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:42:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:11:31
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:30

US3732207

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:42:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:11:31
User entered '27 Aug 2020'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:30

US3732207

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:42:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:11:31
User entered '17:44'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:30

US3732207

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:42:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered '27 Aug 2020 17:44'	System	01 Sep 2020 00:57:30

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:42:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:12:52
User entered '27 Aug 2020'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:48

FDA-CBER-2022-1614-3090663

US3732207

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:21:23

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:42:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:48

US3732207

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:21:23

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:42:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:12:52
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:48

US3732207

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:42:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:12:52
User entered '17:40'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:48

US3732207

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:21:23

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:42:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered '27 Aug 2020 17:40'	System	01 Sep 2020 00:57:48

FDA-CBER-2022-1614-3090667

US3732207

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:21:23

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:42:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:48

US3732207

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:21:23

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:42:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:12:52
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:48

US3732207

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:42:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:12:52
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:48

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:42:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	System	01 Sep 2020 00:57:48

US3732207
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:42:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:13:09
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:57:52

US3732207
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 12 Aug 2021 13:21:23
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:42:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered '1'	System	01 Sep 2020 00:57:52

US3732207
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 12 Aug 2021 13:21:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 01:15:51

US3732207
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 12 Aug 2021 13:21:23
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:37:08', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '15b09c42-819b-4076-965d-b16f1e14a92f'	System	28 Aug 2020 01:41:10
User entered 'Yes (Y)'	System	28 Aug 2020 01:41:10

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:40:53', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '15b09c42-819b-4076-965d-b16f1e14a92f'	System	28 Aug 2020 01:41:10
User entered '97.5'	System	28 Aug 2020 01:41:10

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:41:00', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '15b09c42-819b-4076-965d-b16f1e14a92f'	System	28 Aug 2020 01:41:10
User entered 'No (N)'	System	28 Aug 2020 01:41:10

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:41:03', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '15b09c42-819b-4076-965d-b16f1e14a92f'	System	28 Aug 2020 01:41:10
User entered '27 Aug 2020 18:41'	System	28 Aug 2020 01:41:10

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '27 Aug 2020 18:34'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '27 Aug 2020 21:04'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:04:19', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '52c0e027-49e7-4aca-ab54-bd38c61653f4'	System	28 Aug 2020 07:04:44
User entered 'Yes (Y)'	System	28 Aug 2020 07:04:44

FDA-CBER-2022-1614-3090682

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:04:25', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '52c0e027-49e7-4aca-ab54-bd38c61653f4'	System	28 Aug 2020 07:04:44
User entered '97.7'	System	28 Aug 2020 07:04:44

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:04:30', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '52c0e027-49e7-4aca-ab54-bd38c61653f4'	System	28 Aug 2020 07:04:44
User entered 'No (N)'	System	28 Aug 2020 07:04:44

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:04:41', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '52c0e027-49e7-4aca-ab54-bd38c61653f4'	System	28 Aug 2020 07:04:44
User entered '28 Aug 2020 00:04'	System	28 Aug 2020 07:04:44

Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 12 Aug 2021 13:21:23
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '27 Aug 2020 21:59'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '28 Aug 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 12 Aug 2021 13:21:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 2'	System	28 Aug 2020 01:15:51

FDA-CBER-2022-1614-3090688

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:21:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:19', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '23f5d973-f932-403c-9cca-9e18d00a4657'	System	28 Aug 2020 19:00:32
User entered 'Yes (Y)'	System	28 Aug 2020 19:00:32

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:21:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:22', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '23f5d973-f932-403c-9cca-9e18d00a4657'	System	28 Aug 2020 19:00:32
User entered '97.5'	System	28 Aug 2020 19:00:32

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:25', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '23f5d973-f932-403c-9cca-9e18d00a4657'	System	28 Aug 2020 19:00:32
User entered 'No (N)'	System	28 Aug 2020 19:00:32

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:21:23

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:27', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '23f5d973-f932-403c-9cca-9e18d00a4657'	System	28 Aug 2020 19:00:32
User entered '28 Aug 2020 12:00'	System	28 Aug 2020 19:00:32

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:21:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '28 Aug 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:21:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 12 Aug 2021 13:21:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 3'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:21:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:11:45', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0fdd1635-f108-489c-ab67-4577563116f1'	System	30 Aug 2020 02:12:00
User entered 'Yes (Y)'	System	30 Aug 2020 02:12:00

US3732207
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 12 Aug 2021 13:21:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:11:53', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0fdd1635-f108-489c-ab67-4577563116f1'	System	30 Aug 2020 02:12:00
User entered '97.7'	System	30 Aug 2020 02:12:00

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:11:36', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0fdd1635-f108-489c-ab67-4577563116f1'	System	30 Aug 2020 02:12:00
User entered 'No (N)'	System	30 Aug 2020 02:12:00

US3732207
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 12 Aug 2021 13:21:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:11:57', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0fdd1635-f108-489c-ab67-4577563116f1'	System	30 Aug 2020 02:12:00
User entered '29 Aug 2020 19:11'	System	30 Aug 2020 02:12:00

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:21:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:21:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 12 Aug 2021 13:21:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 4'	System	28 Aug 2020 01:15:51

FDA-CBER-2022-1614-3090702

US3732207
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 12 Aug 2021 13:21:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:03:36', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'a1cc5ee3-7cb2-4cca-b828-1ed2e1fa583f'	System	30 Aug 2020 20:03:51
User entered 'Yes (Y)'	System	30 Aug 2020 20:03:51

US3732207
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 12 Aug 2021 13:21:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:03:41', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'a1cc5ee3-7cb2-4cca-b828-1ed2e1fa583f'	System	30 Aug 2020 20:03:51
User entered '97.7'	System	30 Aug 2020 20:03:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:03:44', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'a1cc5ee3-7cb2-4cca-b828-1ed2e1fa583f'	System	30 Aug 2020 20:03:51
User entered 'No (N)'	System	30 Aug 2020 20:03:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:21:23

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:03:48', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'a1cc5ee3-7cb2-4cca-b828-1ed2e1fa583f'	System	30 Aug 2020 20:03:51
User entered '30 Aug 2020 13:03'	System	30 Aug 2020 20:03:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:21:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:21:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 12 Aug 2021 13:21:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 5'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:21:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:13:31', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'a50540bc-9f1f-48e3-b07f-a40b53b94998'	System	01 Sep 2020 02:13:42
User entered 'Yes (Y)'	System	01 Sep 2020 02:13:42

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:21:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:13:34', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'a50540bc-9f1f-48e3-b07f-a40b53b94998'	System	01 Sep 2020 02:13:42
User entered '97.7'	System	01 Sep 2020 02:13:42

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:21:23

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:13:38', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'a50540bc-9f1f-48e3-b07f-a40b53b94998'	System	01 Sep 2020 02:13:42
User entered 'No (N)'	System	01 Sep 2020 02:13:42

US3732207
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 12 Aug 2021 13:21:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:13:40', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'a50540bc-9f1f-48e3-b07f-a40b53b94998'	System	01 Sep 2020 02:13:42
User entered '31 Aug 2020 19:13'	System	01 Sep 2020 02:13:42

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:21:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:21:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 12 Aug 2021 13:21:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 6'	System	28 Aug 2020 01:15:51

FDA-CBER-2022-1614-3090716

US3732207
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 12 Aug 2021 13:21:23
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:12:31', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '200910d3-d932-41c5-925a-e7ad30db8ddc'	System	01 Sep 2020 19:12:43
User entered 'Yes (Y)'	System	01 Sep 2020 19:12:43

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:21:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:12:37', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '200910d3-d932-41c5-925a-e7ad30db8ddc'	System	01 Sep 2020 19:12:43
User entered '97.5'	System	01 Sep 2020 19:12:43

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:12:38', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '200910d3-d932-41c5-925a-e7ad30db8ddc'	System	01 Sep 2020 19:12:43
User entered 'No (N)'	System	01 Sep 2020 19:12:43

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:21:23

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:12:41', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '200910d3-d932-41c5-925a-e7ad30db8ddc'	System	01 Sep 2020 19:12:43
User entered '01 Sep 2020 12:12'	System	01 Sep 2020 19:12:43

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:21:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:21:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 12 Aug 2021 13:21:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 7'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:21:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:21', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '814119d6-1aca-4f3b-a391-aa36fe0537e6'	System	02 Sep 2020 19:38:34
User entered 'Yes (Y)'	System	02 Sep 2020 19:38:34

US3732207
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 12 Aug 2021 13:21:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:25', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '814119d6-1aca-4f3b-a391-aa36fe0537e6'	System	02 Sep 2020 19:38:34
User entered '97.7'	System	02 Sep 2020 19:38:34

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:30', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '814119d6-1aca-4f3b-a391-aa36fe0537e6'	System	02 Sep 2020 19:38:34
User entered 'No (N)'	System	02 Sep 2020 19:38:34

US3732207
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 12 Aug 2021 13:21:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:32', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '814119d6-1aca-4f3b-a391-aa36fe0537e6'	System	02 Sep 2020 19:38:34
User entered '02 Sep 2020 12:38'	System	02 Sep 2020 19:38:34

US3732207

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:21:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 12 Aug 2021 13:21:23
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 12 Aug 2021 13:21:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:37:24', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '63c5f860-ba45-4415-bd80-5bb37eec269a'	System	28 Aug 2020 01:37:47
User entered 'None (1)'	System	28 Aug 2020 01:37:47

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:37:29', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '63c5f860-ba45-4415-bd80-5bb37eec269a'	System	28 Aug 2020 01:37:47
User entered 'No (N)'	System	28 Aug 2020 01:37:47

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:37:32', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '63c5f860-ba45-4415-bd80-5bb37eec269a'	System	28 Aug 2020 01:37:47
User entered 'No (N)'	System	28 Aug 2020 01:37:47

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:37:39', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '63c5f860-ba45-4415-bd80-5bb37eec269a'	System	28 Aug 2020 01:37:47
User entered 'None (1)'	System	28 Aug 2020 01:37:47

US3732207
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 12 Aug 2021 13:21:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:37:45', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '63c5f860-ba45-4415-bd80-5bb37eec269a'	System	28 Aug 2020 01:37:47
User entered '27 Aug 2020 18:37'	System	28 Aug 2020 01:37:47

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '27 Aug 2020 18:34'	System	28 Aug 2020 01:15:51

FDA-CBER-2022-1614-3090736

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '27 Aug 2020 21:04'	System	28 Aug 2020 01:15:51

FDA-CBER-2022-1614-3090737

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:04:51', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0104e954-3d71-4266-a7e8-061cc53455a0'	System	28 Aug 2020 07:05:05
User entered 'None (1)'	System	28 Aug 2020 07:05:05

US3732207
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:04:54', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0104e954-3d71-4266-a7e8-061cc53455a0'	System	28 Aug 2020 07:05:05
User entered 'No (N)'	System	28 Aug 2020 07:05:05

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:04:57', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0104e954-3d71-4266-a7e8-061cc53455a0'	System	28 Aug 2020 07:05:05
User entered 'No (N)'	System	28 Aug 2020 07:05:05

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:04:59', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0104e954-3d71-4266-a7e8-061cc53455a0'	System	28 Aug 2020 07:05:05
User entered 'None (1)'	System	28 Aug 2020 07:05:05

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:05:02', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0104e954-3d71-4266-a7e8-061cc53455a0'	System	28 Aug 2020 07:05:05
User entered '28 Aug 2020 00:05'	System	28 Aug 2020 07:05:05

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '27 Aug 2020 21:59'	System	28 Aug 2020 01:15:51

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '28 Aug 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 12 Aug 2021 13:21:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 2'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:21:23

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:30', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '9b22c852-8aee-4126-aa07-91998ca4a7d8'	System	28 Aug 2020 19:00:40
User entered 'None (1)'	System	28 Aug 2020 19:00:40

US3732207
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 12 Aug 2021 13:21:23
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:32', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '9b22c852-8aee-4126-aa07-91998ca4a7d8'	System	28 Aug 2020 19:00:40
User entered 'No (N)'	System	28 Aug 2020 19:00:40

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:33', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '9b22c852-8aee-4126-aa07-91998ca4a7d8'	System	28 Aug 2020 19:00:40
User entered 'No (N)'	System	28 Aug 2020 19:00:40

FDA-CBER-2022-1614-3090749

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:21:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:35', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '9b22c852-8aee-4126-aa07-91998ca4a7d8'	System	28 Aug 2020 19:00:40
User entered 'None (1)'	System	28 Aug 2020 19:00:40

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:21:23

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:36', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '9b22c852-8aee-4126-aa07-91998ca4a7d8'	System	28 Aug 2020 19:00:40
User entered '28 Aug 2020 12:00'	System	28 Aug 2020 19:00:40

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '28 Aug 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:21:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 12 Aug 2021 13:21:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 3'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:12:02', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'c3ae564c-84b7-4169-a276-e78bb69bb320'	System	30 Aug 2020 02:12:15
User entered 'None (1)'	System	30 Aug 2020 02:12:15

US3732207
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 12 Aug 2021 13:21:23
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:12:05', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'c3ae564c-84b7-4169-a276-e78bb69bb320'	System	30 Aug 2020 02:12:15
User entered 'No (N)'	System	30 Aug 2020 02:12:15

US3732207
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 12 Aug 2021 13:21:23
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:12:06', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'c3ae564c-84b7-4169-a276-e78bb69bb320'	System	30 Aug 2020 02:12:15
User entered 'No (N)'	System	30 Aug 2020 02:12:15

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:21:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:12:08', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'c3ae564c-84b7-4169-a276-e78bb69bb320'	System	30 Aug 2020 02:12:15
User entered 'None (1)'	System	30 Aug 2020 02:12:15

US3732207
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 12 Aug 2021 13:21:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:12:11', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'c3ae564c-84b7-4169-a276-e78bb69bb320'	System	30 Aug 2020 02:12:15
User entered '29 Aug 2020 19:12'	System	30 Aug 2020 02:12:15

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:21:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 12 Aug 2021 13:21:23
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 4'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:21:23

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:03:52', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '8ac5e47b-10d3-4fa2-8b6c-79b691c1e24b'	System	30 Aug 2020 20:04:01
User entered 'None (1)'	System	30 Aug 2020 20:04:01

US3732207
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 12 Aug 2021 13:21:23
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:03:54', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '8ac5e47b-10d3-4fa2-8b6c-79b691c1e24b'	System	30 Aug 2020 20:04:01
User entered 'No (N)'	System	30 Aug 2020 20:04:01

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:03:55', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '8ac5e47b-10d3-4fa2-8b6c-79b691c1e24b'	System	30 Aug 2020 20:04:01
User entered 'No (N)'	System	30 Aug 2020 20:04:01

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:21:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:03:57', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '8ac5e47b-10d3-4fa2-8b6c-79b691c1e24b'	System	30 Aug 2020 20:04:01
User entered 'None (1)'	System	30 Aug 2020 20:04:01

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:21:23

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:03:59', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '8ac5e47b-10d3-4fa2-8b6c-79b691c1e24b'	System	30 Aug 2020 20:04:01
User entered '30 Aug 2020 13:03'	System	30 Aug 2020 20:04:01

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:21:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:21:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 12 Aug 2021 13:21:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 5'	System	28 Aug 2020 01:15:51

US3732207
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 12 Aug 2021 13:21:23

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:13:44', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '833019df-8a78-4868-b23c-20cb53069403'	System	01 Sep 2020 02:14:06
User entered 'None (1)'	System	01 Sep 2020 02:14:06

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:13:47', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '833019df-8a78-4868-b23c-20cb53069403'	System	01 Sep 2020 02:14:06
User entered 'No (N)'	System	01 Sep 2020 02:14:06

US3732207
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 12 Aug 2021 13:21:23
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:13:53', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '833019df-8a78-4868-b23c-20cb53069403'	System	01 Sep 2020 02:14:06
User entered 'No (N)'	System	01 Sep 2020 02:14:06

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:13:59', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '833019df-8a78-4868-b23c-20cb53069403'	System	01 Sep 2020 02:14:06
User entered 'None (1)'	System	01 Sep 2020 02:14:06

US3732207
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 12 Aug 2021 13:21:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:14:01', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '833019df-8a78-4868-b23c-20cb53069403'	System	01 Sep 2020 02:14:06
User entered '31 Aug 2020 19:14'	System	01 Sep 2020 02:14:06

US3732207
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 12 Aug 2021 13:21:23
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:21:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 01:15:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 6'	System	28 Aug 2020 01:15:51

FDA-CBER-2022-1614-3090778

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:12:44', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '614d590e-6bfd-460f-bfc4-834cdac2474f'	System	01 Sep 2020 19:12:53
User entered 'None (1)'	System	01 Sep 2020 19:12:53

FDA-CBER-2022-1614-3090779

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:12:47', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '614d590e-6bfd-460f-bfc4-834cdac2474f'	System	01 Sep 2020 19:12:53
User entered 'No (N)'	System	01 Sep 2020 19:12:53

US3732207
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 12 Aug 2021 13:21:23
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:12:48', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '614d590e-6bfd-460f-bfc4-834cdac2474f'	System	01 Sep 2020 19:12:53
User entered 'No (N)'	System	01 Sep 2020 19:12:53

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:21:23

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:12:50', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '614d590e-6bfd-460f-bfc4-834cdac2474f'	System	01 Sep 2020 19:12:53
User entered 'None (1)'	System	01 Sep 2020 19:12:53

FDA-CBER-2022-1614-3090782

US3732207
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 12 Aug 2021 13:21:23

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:12:52', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '614d590e-6bfd-460f-bfc4-834cdac2474f'	System	01 Sep 2020 19:12:53
User entered '01 Sep 2020 12:12'	System	01 Sep 2020 19:12:53

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:21:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:21:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 12 Aug 2021 13:21:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 7'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:35', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'f42abb61-7ab3-469f-ae7d-d2e5ac48404c'	System	02 Sep 2020 19:38:48
User entered 'None (1)'	System	02 Sep 2020 19:38:48

US3732207
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 12 Aug 2021 13:21:23
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:42', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'f42abb61-7ab3-469f-ae7d-d2e5ac48404c'	System	02 Sep 2020 19:38:48
User entered 'No (N)'	System	02 Sep 2020 19:38:48

US3732207
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 12 Aug 2021 13:21:23
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:43', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'f42abb61-7ab3-469f-ae7d-d2e5ac48404c'	System	02 Sep 2020 19:38:48
User entered 'No (N)'	System	02 Sep 2020 19:38:48

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:44', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'f42abb61-7ab3-469f-ae7d-d2e5ac48404c'	System	02 Sep 2020 19:38:48
User entered 'None (1)'	System	02 Sep 2020 19:38:48

US3732207
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 12 Aug 2021 13:21:23
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:46', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'f42abb61-7ab3-469f-ae7d-d2e5ac48404c'	System	02 Sep 2020 19:38:48
User entered '02 Sep 2020 12:38'	System	02 Sep 2020 19:38:48

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:21:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:21:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 12 Aug 2021 13:21:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:41:25', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3b20906c-3488-476a-a154-f92df58df552'	System	28 Aug 2020 01:41:56
User entered 'No interference with activity (1)'	System	28 Aug 2020 01:41:56

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 12 Aug 2021 13:21:23
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:41:29', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3b20906c-3488-476a-a154-f92df58df552'	System	28 Aug 2020 01:41:56
User entered 'None (0)'	System	28 Aug 2020 01:41:56

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 12 Aug 2021 13:21:23
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:41:34', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3b20906c-3488-476a-a154-f92df58df552'	System	28 Aug 2020 01:41:56
User entered 'None (0)'	System	28 Aug 2020 01:41:56

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:41:37', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3b20906c-3488-476a-a154-f92df58df552'	System	28 Aug 2020 01:41:56
User entered 'None (0)'	System	28 Aug 2020 01:41:56

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 12 Aug 2021 13:21:23
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:41:41', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3b20906c-3488-476a-a154-f92df58df552'	System	28 Aug 2020 01:41:56
User entered 'None (0)'	System	28 Aug 2020 01:41:56

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 12 Aug 2021 13:21:23
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:41:43', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3b20906c-3488-476a-a154-f92df58df552'	System	28 Aug 2020 01:41:56
User entered 'None (0)'	System	28 Aug 2020 01:41:56

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:41:51', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3b20906c-3488-476a-a154-f92df58df552'	System	28 Aug 2020 01:41:56
User entered 'No (N)'	System	28 Aug 2020 01:41:56

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-27T18:41:53', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3b20906c-3488-476a-a154-f92df58df552'	System	28 Aug 2020 01:41:56
User entered '27 Aug 2020 18:41'	System	28 Aug 2020 01:41:56

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '27 Aug 2020 18:34'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '27 Aug 2020 21:04'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 01:15:51

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 12 Aug 2021 13:21:23
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:05:06', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '5681309a-5db7-4a68-87ff-ed9a66958d33'	System	28 Aug 2020 07:05:26
User entered 'None (0)'	System	28 Aug 2020 07:05:26

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 12 Aug 2021 13:21:23
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:05:08', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '5681309a-5db7-4a68-87ff-ed9a66958d33'	System	28 Aug 2020 07:05:26
User entered 'None (0)'	System	28 Aug 2020 07:05:26

FDA-CBER-2022-1614-3090807

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 12 Aug 2021 13:21:23
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:05:10', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '5681309a-5db7-4a68-87ff-ed9a66958d33'	System	28 Aug 2020 07:05:26
User entered 'None (0)'	System	28 Aug 2020 07:05:26

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 12 Aug 2021 13:21:23
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:05:12', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '5681309a-5db7-4a68-87ff-ed9a66958d33'	System	28 Aug 2020 07:05:26
User entered 'None (0)'	System	28 Aug 2020 07:05:26

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:05:14', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '5681309a-5db7-4a68-87ff-ed9a66958d33'	System	28 Aug 2020 07:05:26
User entered 'None (0)'	System	28 Aug 2020 07:05:26

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:05:16', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '5681309a-5db7-4a68-87ff-ed9a66958d33'	System	28 Aug 2020 07:05:26
User entered 'None (0)'	System	28 Aug 2020 07:05:26

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:05:20', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '5681309a-5db7-4a68-87ff-ed9a66958d33'	System	28 Aug 2020 07:05:26
User entered 'No (N)'	System	28 Aug 2020 07:05:26

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T00:05:22', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '5681309a-5db7-4a68-87ff-ed9a66958d33'	System	28 Aug 2020 07:05:26
User entered '28 Aug 2020 00:05'	System	28 Aug 2020 07:05:26

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '27 Aug 2020 21:59'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '28 Aug 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 12 Aug 2021 13:21:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 2'	System	28 Aug 2020 01:15:51

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 12 Aug 2021 13:21:23
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:40', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3fb0b33a-b9b0-43c1-8b1f-67cb825da843'	System	28 Aug 2020 19:00:56
User entered 'None (0)'	System	28 Aug 2020 19:00:56

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 12 Aug 2021 13:21:23
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:41', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3fb0b33a-b9b0-43c1-8b1f-67cb825da843'	System	28 Aug 2020 19:00:56
User entered 'None (0)'	System	28 Aug 2020 19:00:56

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 12 Aug 2021 13:21:23
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:42', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3fb0b33a-b9b0-43c1-8b1f-67cb825da843'	System	28 Aug 2020 19:00:56
User entered 'None (0)'	System	28 Aug 2020 19:00:56

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:44', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3fb0b33a-b9b0-43c1-8b1f-67cb825da843'	System	28 Aug 2020 19:00:56
User entered 'None (0)'	System	28 Aug 2020 19:00:56

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 12 Aug 2021 13:21:23
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:45', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3fb0b33a-b9b0-43c1-8b1f-67cb825da843'	System	28 Aug 2020 19:00:56
User entered 'None (0)'	System	28 Aug 2020 19:00:56

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 12 Aug 2021 13:21:23
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:46', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3fb0b33a-b9b0-43c1-8b1f-67cb825da843'	System	28 Aug 2020 19:00:56
User entered 'None (0)'	System	28 Aug 2020 19:00:56

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:49', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3fb0b33a-b9b0-43c1-8b1f-67cb825da843'	System	28 Aug 2020 19:00:56
User entered 'No (N)'	System	28 Aug 2020 19:00:56

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-28T12:00:51', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '3fb0b33a-b9b0-43c1-8b1f-67cb825da843'	System	28 Aug 2020 19:00:56
User entered '28 Aug 2020 12:00'	System	28 Aug 2020 19:00:56

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '28 Aug 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 3'	System	28 Aug 2020 01:15:51

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 12 Aug 2021 13:21:23
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:12:33', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'ff6d2760-f426-4778-94b9-b22b1abe8646'	System	30 Aug 2020 02:13:09
User entered 'None (0)'	System	30 Aug 2020 02:13:09

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 12 Aug 2021 13:21:23
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:12:31', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'ff6d2760-f426-4778-94b9-b22b1abe8646'	System	30 Aug 2020 02:13:09
User entered 'Some interference with activity (2)'	System	30 Aug 2020 02:13:09

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:12:34', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'ff6d2760-f426-4778-94b9-b22b1abe8646'	System	30 Aug 2020 02:13:09
User entered 'None (0)'	System	30 Aug 2020 02:13:09

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 12 Aug 2021 13:21:23
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:12:37', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'ff6d2760-f426-4778-94b9-b22b1abe8646'	System	30 Aug 2020 02:13:09
User entered 'None (0)'	System	30 Aug 2020 02:13:09

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 12 Aug 2021 13:21:23
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:12:39', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'ff6d2760-f426-4778-94b9-b22b1abe8646'	System	30 Aug 2020 02:13:09
User entered 'None (0)'	System	30 Aug 2020 02:13:09

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:12:52', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'ff6d2760-f426-4778-94b9-b22b1abe8646'	System	30 Aug 2020 02:13:09
User entered 'None (0)'	System	30 Aug 2020 02:13:09

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:13:01', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'ff6d2760-f426-4778-94b9-b22b1abe8646'	System	30 Aug 2020 02:13:09
User entered 'No (N)'	System	30 Aug 2020 02:13:09

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-29T19:13:04', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'ff6d2760-f426-4778-94b9-b22b1abe8646'	System	30 Aug 2020 02:13:09
User entered '29 Aug 2020 19:13'	System	30 Aug 2020 02:13:09

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 12 Aug 2021 13:21:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 4'	System	28 Aug 2020 01:15:51

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 12 Aug 2021 13:21:23
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:04:04', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'f28a4233-ecec-4731-95f8-225180ae2c14'	System	30 Aug 2020 20:04:18
User entered 'None (0)'	System	30 Aug 2020 20:04:18

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 12 Aug 2021 13:21:23
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:04:06', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'f28a4233-ecec-4731-95f8-225180ae2c14'	System	30 Aug 2020 20:04:18
User entered 'None (0)'	System	30 Aug 2020 20:04:18

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 12 Aug 2021 13:21:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:04:07', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'f28a4233-ecec-4731-95f8-225180ae2c14'	System	30 Aug 2020 20:04:18
User entered 'None (0)'	System	30 Aug 2020 20:04:18

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:04:08', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'f28a4233-ecec-4731-95f8-225180ae2c14'	System	30 Aug 2020 20:04:18
User entered 'None (0)'	System	30 Aug 2020 20:04:18

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 12 Aug 2021 13:21:23
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:04:09', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'f28a4233-ecec-4731-95f8-225180ae2c14'	System	30 Aug 2020 20:04:18
User entered 'None (0)'	System	30 Aug 2020 20:04:18

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:04:10', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'f28a4233-ecec-4731-95f8-225180ae2c14'	System	30 Aug 2020 20:04:18
User entered 'None (0)'	System	30 Aug 2020 20:04:18

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 12 Aug 2021 13:21:23
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:04:13', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'f28a4233-ecec-4731-95f8-225180ae2c14'	System	30 Aug 2020 20:04:18
User entered 'No (N)'	System	30 Aug 2020 20:04:18

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-30T13:04:15', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: 'f28a4233-ecec-4731-95f8-225180ae2c14'	System	30 Aug 2020 20:04:18
User entered '30 Aug 2020 13:04'	System	30 Aug 2020 20:04:18

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 01:15:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 5'	System	28 Aug 2020 01:15:51

FDA-CBER-2022-1614-3090849

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 12 Aug 2021 13:21:23
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:14:04', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '279255bf-d6eb-4bc0-b60a-8b77ce93b052'	System	01 Sep 2020 02:14:23
User entered 'None (0)'	System	01 Sep 2020 02:14:23

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 12 Aug 2021 13:21:23
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:14:06', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '279255bf-d6eb-4bc0-b60a-8b77ce93b052'	System	01 Sep 2020 02:14:23
User entered 'None (0)'	System	01 Sep 2020 02:14:23

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 12 Aug 2021 13:21:23
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:14:08', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '279255bf-d6eb-4bc0-b60a-8b77ce93b052'	System	01 Sep 2020 02:14:23
User entered 'None (0)'	System	01 Sep 2020 02:14:23

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:14:10', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '279255bf-d6eb-4bc0-b60a-8b77ce93b052'	System	01 Sep 2020 02:14:23
User entered 'None (0)'	System	01 Sep 2020 02:14:23

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:14:12', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '279255bf-d6eb-4bc0-b60a-8b77ce93b052'	System	01 Sep 2020 02:14:23
User entered 'None (0)'	System	01 Sep 2020 02:14:23

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 12 Aug 2021 13:21:23
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:14:14', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '279255bf-d6eb-4bc0-b60a-8b77ce93b052'	System	01 Sep 2020 02:14:23
User entered 'None (0)'	System	01 Sep 2020 02:14:23

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:14:16', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '279255bf-d6eb-4bc0-b60a-8b77ce93b052'	System	01 Sep 2020 02:14:23
User entered 'No (N)'	System	01 Sep 2020 02:14:23

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-08-31T19:14:20', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '279255bf-d6eb-4bc0-b60a-8b77ce93b052'	System	01 Sep 2020 02:14:23
User entered '31 Aug 2020 19:14'	System	01 Sep 2020 02:14:23

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 12 Aug 2021 13:21:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 6'	System	28 Aug 2020 01:15:51

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 12 Aug 2021 13:21:23
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:12:54', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '80c56e42-b59c-4a85-9f18-0336947c5650'	System	01 Sep 2020 19:13:08
User entered 'None (0)'	System	01 Sep 2020 19:13:08

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 12 Aug 2021 13:21:23
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:12:56', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '80c56e42-b59c-4a85-9f18-0336947c5650'	System	01 Sep 2020 19:13:08
User entered 'None (0)'	System	01 Sep 2020 19:13:08

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 12 Aug 2021 13:21:23
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:12:57', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '80c56e42-b59c-4a85-9f18-0336947c5650'	System	01 Sep 2020 19:13:08
User entered 'None (0)'	System	01 Sep 2020 19:13:08

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:12:58', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '80c56e42-b59c-4a85-9f18-0336947c5650'	System	01 Sep 2020 19:13:08
User entered 'None (0)'	System	01 Sep 2020 19:13:08

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 12 Aug 2021 13:21:23
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:12:59', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '80c56e42-b59c-4a85-9f18-0336947c5650'	System	01 Sep 2020 19:13:08
User entered 'None (0)'	System	01 Sep 2020 19:13:08

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 12 Aug 2021 13:21:23
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:13:01', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '80c56e42-b59c-4a85-9f18-0336947c5650'	System	01 Sep 2020 19:13:08
User entered 'None (0)'	System	01 Sep 2020 19:13:08

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 12 Aug 2021 13:21:23
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:13:03', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '80c56e42-b59c-4a85-9f18-0336947c5650'	System	01 Sep 2020 19:13:08
User entered 'No (N)'	System	01 Sep 2020 19:13:08

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-01T12:13:05', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '80c56e42-b59c-4a85-9f18-0336947c5650'	System	01 Sep 2020 19:13:08
User entered '01 Sep 2020 12:13'	System	01 Sep 2020 19:13:08

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 12 Aug 2021 13:21:23
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
Data entry locked.	System	28 Aug 2020 01:15:51
User entered 'Day 7'	System	28 Aug 2020 01:15:51

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 12 Aug 2021 13:21:23
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:49', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0e9601bb-6e0f-4b67-b833-116567050cb2'	System	02 Sep 2020 19:39:04
User entered 'None (0)'	System	02 Sep 2020 19:39:04

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 12 Aug 2021 13:21:23
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:50', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0e9601bb-6e0f-4b67-b833-116567050cb2'	System	02 Sep 2020 19:39:04
User entered 'None (0)'	System	02 Sep 2020 19:39:04

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 12 Aug 2021 13:21:23
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:51', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0e9601bb-6e0f-4b67-b833-116567050cb2'	System	02 Sep 2020 19:39:04
User entered 'None (0)'	System	02 Sep 2020 19:39:04

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 12 Aug 2021 13:21:23
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:52', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0e9601bb-6e0f-4b67-b833-116567050cb2'	System	02 Sep 2020 19:39:04
User entered 'None (0)'	System	02 Sep 2020 19:39:04

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 12 Aug 2021 13:21:23
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:53', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0e9601bb-6e0f-4b67-b833-116567050cb2'	System	02 Sep 2020 19:39:04
User entered 'None (0)'	System	02 Sep 2020 19:39:04

US3732207
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 12 Aug 2021 13:21:23
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:55', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0e9601bb-6e0f-4b67-b833-116567050cb2'	System	02 Sep 2020 19:39:04
User entered 'None (0)'	System	02 Sep 2020 19:39:04

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:56', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0e9601bb-6e0f-4b67-b833-116567050cb2'	System	02 Sep 2020 19:39:04
User entered 'No (N)'	System	02 Sep 2020 19:39:04

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:21:23

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FAA0D279-D9AB-43E0-A4AA-7597AB39277B)', Time: '2020-09-02T12:38:58', User OID: 'PatientReportedOutcome (US3732207)', ODM File OID: '0e9601bb-6e0f-4b67-b833-116567050cb2'	System	02 Sep 2020 19:39:04
User entered '02 Sep 2020 12:38'	System	02 Sep 2020 19:39:04

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:21:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 01:15:51

US3732207

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:21:23

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:46:35
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 01:15:51

US3732207

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:43:20
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:14:21
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	03 Sep 2020 22:21:05

US3732207

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:43:20
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:14:21
User entered '03 Sep 2020'	Linda Vega (b) (4) (b) (4)	03 Sep 2020 22:21:05

US3732207
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 12 Aug 2021 13:21:23
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:43:20
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:14:21
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4) (b) (4)	03 Sep 2020 22:21:05

US3732207

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:43:20
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:14:21
User entered empty.	Linda Vega (b) (4) (b) (4)	03 Sep 2020 22:21:05

US3732207
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:43:26
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:14:32
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	03 Sep 2020 22:21:09

US3732207

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:43:26
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered '1'	System	03 Sep 2020 22:21:09

US3732207

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:43:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:15:03
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	11 Sep 2020 16:32:49

US3732207

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:43:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:15:03
User entered '10 Sep 2020'	Linda Vega (b) (4) (b) (4)	11 Sep 2020 16:32:49

US3732207
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 12 Aug 2021 13:21:23
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:43:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:15:03
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4) (b) (4)	11 Sep 2020 16:32:49

US3732207

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:43:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:15:03
User entered empty.	Linda Vega (b) (4) (b) (4)	11 Sep 2020 16:32:49

US3732207
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:43:48
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:15:10
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	11 Sep 2020 16:32:53

US3732207

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:43:48
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered '1'	System	11 Sep 2020 16:32:53

US3732207

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:44:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:15:47
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	18 Sep 2020 19:23:55

US3732207

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:44:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:15:47
User entered '18 Sep 2020'	Linda Vega (b) (4) (b) (4)	18 Sep 2020 19:23:55

US3732207
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 12 Aug 2021 13:21:23

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:44:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:15:47
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4) (b) (4)	18 Sep 2020 19:23:55

US3732207

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:44:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:15:47
User entered empty.	Linda Vega (b) (4) (b) (4)	18 Sep 2020 19:23:55

US3732207

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:44:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:15:54
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	18 Sep 2020 19:23:46

US3732207

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 06:44:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered '1'	System	18 Sep 2020 19:23:46

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User accepted default value 'Pre-Dose (PREDOSE)'	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 22:59:27

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 22:59:27

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 22:59:27

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 22:59:27

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	System	15 Mar 2021 22:59:27

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 22:59:27

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 22:59:27

US3732207
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 12 Aug 2021 13:21:23
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 22:59:27

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 22:59:27

US3732207
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 12 Aug 2021 13:21:23
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	System	15 Mar 2021 22:59:27

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 22:59:27

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	System	15 Mar 2021 22:59:27

FDA-CBER-2022-1614-3090911

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 22:59:27

FDA-CBER-2022-1614-3090912

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	System	15 Mar 2021 22:59:27

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 22:59:27

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	System	15 Mar 2021 22:59:27

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User accepted default value 'Post-Dose (POSTDOSE)'	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 22:59:27

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 22:59:27

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 22:59:27

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 22:59:27

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	System	15 Mar 2021 22:59:27

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 22:59:27

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 22:59:27

US3732207
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 12 Aug 2021 13:21:23
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 22:59:27

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 22:59:27

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 12 Aug 2021 13:21:23
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	System	15 Mar 2021 22:59:27

FDA-CBER-2022-1614-3090925

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 22:59:27

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	System	15 Mar 2021 22:59:27

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 22:59:27

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	System	15 Mar 2021 22:59:27

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 22:59:27

US3732207

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:15
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	System	15 Mar 2021 22:59:27

US3732207

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:21
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 22:59:22

FDA-CBER-2022-1614-3090932

US3732207

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:21
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 22:59:22

US3732207

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:25
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 23:00:18

US3732207
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 12 Aug 2021 13:21:23
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:25
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered 'Other (OTHER)'	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 23:00:18

US3732207

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:25
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered 'Subject did not qualify for second injection due to AE symptomatic covid'	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 23:00:18

US3732207
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 12 Aug 2021 13:21:23
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:25
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	System	15 Mar 2021 23:00:18

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:25
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 23:00:18

US3732207
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 12 Aug 2021 13:21:23

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:25
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 23:00:18

US3732207

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:25
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	System	15 Mar 2021 23:00:18

US3732207
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 12 Aug 2021 13:21:23
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:25
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 23:00:18

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:25
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	System	15 Mar 2021 23:00:18

US3732207
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 12 Aug 2021 13:21:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:25
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	System	15 Mar 2021 23:00:18

US3732207

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:30
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 23:00:54

US3732207

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:30
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 23:00:54

US3732207

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:30
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 23:00:54

US3732207

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	System	15 Mar 2021 23:00:54

FDA-CBER-2022-1614-3090947

US3732207

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:21:23

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:35
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 23:01:02

US3732207

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:21:23

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 23:01:02

US3732207
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 12 Aug 2021 13:21:23
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:35
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 23:01:02

US3732207

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:35
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 23:01:02

US3732207

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:21:23

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	System	15 Mar 2021 23:01:02

US3732207

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:21:23

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 23:01:02

US3732207

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:21:23

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:35
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered 'No (N)'	Amara Yilmaz (b) (4)	15 Mar 2021 23:01:02

US3732207

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:35
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	15 Mar 2021 23:01:02

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:21:23

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	System	15 Mar 2021 23:01:02

Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:40
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:42:13
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 03:42:03
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:28:25
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 19:03:01

FDA-CBER-2022-1614-3090957

US3732207

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:59
Data hard unlocked.	(b) (4), (b) (6)	12 Apr 2021 14:27:40
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:46:13
User entered empty.	System	07 Oct 2020 19:03:01

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: COVID-19 Contact
Generated On: 12 Aug 2021 13:21:23
Date of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:36:27
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:17:11
User entered '18 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 01:19:59

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: COVID-19 Contact
Generated On: 12 Aug 2021 13:21:23
Time of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:36:27
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:17:11
User entered '10:21'	(b) (4), (b) (6)	23 Sep 2020 01:19:59

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:21:23

Date and Time of Contact (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:36:27
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered '18 Sep 2020 10:21'	System	23 Sep 2020 01:19:59

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: COVID-19 Contact
Generated On: 12 Aug 2021 13:21:23

Type of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:36:27
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:17:11
User entered 'Safety Call (Safety Call)'	(b) (4), (b) (6)	23 Sep 2020 01:19:59

Has the subject reported symptoms of SARS-COV-2?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:36:27
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:17:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 01:19:59

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	24 Feb 2021 02:07:34
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Lauren Arnett (b) (4)	25 Nov 2020 19:28:28
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:26:31
User entered '19 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:26:32
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:26:34
User entered '97'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered '%'	System	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:26:38
User entered '99.0' F	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:19:45
User closed query 'Per Source, "Chills = Moderate". Please re-confirm with Source and Correct.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 06:19:35
Query 'Per Source, "Chills = Moderate". Please re-confirm with Source and Correct.' answered by data change (Site from CRA).	System	10 Nov 2020 03:28:35
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 03:28:35
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 03:28:35
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User opened query 'Per Source, "Chills = Moderate". Please re-confirm with Source and Correct.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 22:24:12
DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 22:23:17
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:23:16
User entered 'Mild (Mild)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:19:42
User closed query 'Per Source, "Cough = None". Please re-confirm with Source and Correct.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 06:19:37
Query 'Per Source, "Cough = None". Please re-confirm with Source and Correct.' answered by data change (Site from CRA).	System	10 Nov 2020 03:28:43
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 03:28:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 03:28:43
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User opened query 'Per Source, "Cough = None". Please re-confirm with Source and Correct.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 22:25:01
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:26:42
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (1)
Generated On: 12 Aug 2021 13:21:23
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:26:43
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:26:45
User entered 'Severe (Severe)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:26:46
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:26:48
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (1)
Generated On: 12 Aug 2021 13:21:23
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:26:50
User entered 'Mild (Mild)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:26:57
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:26:59
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:27:01
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (1)
Generated On: 12 Aug 2021 13:21:23
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:27:02
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:27:04
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:27:09
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:27:11
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:21:23

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:27:12
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	24 Sep 2020 20:42:46

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 02:07:34
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Lauren Arnett (b) (4)	25 Nov 2020 19:28:28
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (2)
Generated On: 12 Aug 2021 13:21:23
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:37:36
User entered '20 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:37:37
User entered '1'	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:37:39
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered empty.	System	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:37:40
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:37:42
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:37:43
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:37:44
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:37:46
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:37:47
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:37:49
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:37:50
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:37:51
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:37:53
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:37:55
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:37:56
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:37:59
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:38:00
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:38:01
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:38:03
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:21:23

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:38:04
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 20:45:30

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 02:07:34
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Lauren Arnett (b) (4)	25 Nov 2020 19:28:28
User entered 'Day 4 (Day 4)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (3)
Generated On: 12 Aug 2021 13:21:23
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:48:01
User entered '21 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:48:03
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:48:05
User entered '96'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (3)
Generated On: 12 Aug 2021 13:21:23
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered '%'	System	24 Sep 2020 20:49:55

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (3)
Generated On: 12 Aug 2021 13:21:23
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:15:48
User entered '101.0' F	(b) (4), (b) (6)	24 Sep 2020 20:49:55

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:16:56
User entered 'Severe (Severe)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:16:58
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:17:04
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:17:10
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

FDA-CBER-2022-1614-3091017

Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (3)
Generated On: 12 Aug 2021 13:21:23
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:17:19
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:17:24
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:17:33
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:17:38
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

FDA-CBER-2022-1614-3091021

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:17:43
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:17:45
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:17:57
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

FDA-CBER-2022-1614-3091024

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:19:16
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:19:19
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:19:29
User entered 'None (None)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:19:32
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

FDA-CBER-2022-1614-3091028

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:21:23

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:17:52
User entered 'Mild (Mild)'	(b) (4), (b) (6)	24 Sep 2020 20:49:55

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (4)
Generated On: 12 Aug 2021 13:21:23
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 02:07:34
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:28:28
User entered 'Day 5 (Day 5)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:22:20
User entered '22 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:22:22
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (4)
Generated On: 12 Aug 2021 13:21:23
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:22:25
User entered '96'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (4)
Generated On: 12 Aug 2021 13:21:23
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered '%'	System	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:22:28
User entered '99.0' F	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (4)
Generated On: 12 Aug 2021 13:21:23
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:20:03
User closed query 'Per Source, "Chills = Severe". Please re-confirm with Source and Correct.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 06:20:01
Query 'Per Source, "Chills = Severe". Please re-confirm with Source and Correct.' answered by data change (Site from CRA).	System	10 Nov 2020 03:29:29
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 03:29:29
User entered 'Severe (Severe)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 03:29:29
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User opened query 'Per Source, "Chills = Severe". Please re-confirm with Source and Correct.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 23:23:43
DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 23:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:22:30
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:22:31
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:24:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (4)
Generated On: 12 Aug 2021 13:21:23
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:24:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:24:13
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:24:18
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:24:21
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:24:25
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:24:43
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:24:44
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:24:58
User entered 'Mild (Mild)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:25:03
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:25:07
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:21:23

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:25:09
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:25:14
User entered 'Mild (Mild)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:24:54
User entered 'None (None)'	(b) (4), (b) (6)	30 Sep 2020 21:01:18

FDA-CBER-2022-1614-3091051

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 02:07:34
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:28:28
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

FDA-CBER-2022-1614-3091052

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (5)
Generated On: 12 Aug 2021 13:21:23

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
User closed query 'Per CDM: Please confirm initial start date of symptoms is the same as teh Contact date (18SEP2020) or update accordingly' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:08:19
Query 'Per CDM: Please confirm initial start date of symptoms is the same as teh Contact date (18SEP2020) or update accordingly' answered with 'Correct as is. Site was unaware of onset of symptoms until called subject for their Day 22 safety call and subject returned same day of staffs awareness of symptoms' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 03:31:11
User opened query 'Per CDM: Please confirm initial start date of symptoms is the same as teh Contact date (18SEP2020) or update accordingly' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 05:58:53
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:28
User entered '18 Sep 2020'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:20:30
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:20:31
User entered '96'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (5)
Generated On: 12 Aug 2021 13:21:23
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered '%'	System	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:20:33
User entered '97.5' F	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:20:34
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:20:36
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:37
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

FDA-CBER-2022-1614-3091060

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:38
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:40
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (5)
Generated On: 12 Aug 2021 13:21:23

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:41
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:43
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

FDA-CBER-2022-1614-3091064

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:44
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:46
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:20:47
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:20:49
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:50
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:51
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:53
User entered 'None (None)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:54
User entered 'Mild (Mild)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

FDA-CBER-2022-1614-3091072

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:21:23

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 22:20:56
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	07 Oct 2020 19:12:37

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 02:08:45
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:28:28
User entered 'Day 6 (Day 6)'	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (6)
Generated On: 12 Aug 2021 13:21:23
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 00:03:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 00:03:27
User entered '23 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 00:03:27
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 00:03:11
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered '1'	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (6)
Generated On: 12 Aug 2021 13:21:23
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered empty.	System	15 Oct 2020 00:03:11

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

FDA-CBER-2022-1614-3091086

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (6)
Generated On: 12 Aug 2021 13:21:23

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

FDA-CBER-2022-1614-3091092

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:21:23

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:34:52
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:11

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 02:00:41
User entered 'Day 1 (Day 1)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:22

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:03:31
User closed query 'Per Source, "Symptoms" Started on 14-SEP-2020. Is Start Date for Day 1 = 14-SEP-2020?' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 21:03:29
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
Query 'Per Source, "Symptoms" Started on 14-SEP-2020. Is Start Date for Day 1 = 14-SEP-2020?' answered with 'Day 1 on 14 SEP 2020 entered.' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 17:28:50
User opened query 'Per Source, "Symptoms" Started on 14-SEP-2020. Is Start Date for Day 1 = 14-SEP-2020?' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 00:24:16
User entered '15 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:22

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:03:33
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered '0'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:22

FDA-CBER-2022-1614-3091098

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:03:38
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered missing code ND - Not Done.	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:22

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (16)
Generated On: 12 Aug 2021 13:21:23
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered '%'	System	25 Nov 2020 19:26:22

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (16)
Generated On: 12 Aug 2021 13:21:23
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:20:49
User closed query 'Subject reported "Fever" starting on 14-SEP-2020 (99F)"; however, we should see Fever/Temperature of "99 F" until the Subject comes into the Site on 18-SEP-2020. Please update Temperature for Day 2 - 15/SEP/2020.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 23:20:40
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Query 'Subject reported "Fever" starting on 14-SEP-2020 (99F)"; however, we should see Fever/Temperature of "99 F" until the Subject comes into the Site on 18-SEP-2020. Please update Temperature for Day 2 - 15/SEP/2020.' answered with 'Updated per request.' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 23:12:45
Signature has been broken.	(b) (4), (b) (6)	16 Mar 2021 22:57:13
User entered '99.0' F reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 22:57:13
User opened query 'Subject reported "Fever" starting on 14-SEP-2020 (99F)"; however, we should see Fever/Temperature of "99 F" until the Subject comes into the Site on 18-SEP-2020. Please update Temperature for Day 2 - 15/SEP/2020.' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 21:05:38
User closed query 'CRA cannot locate in Source, where Temperature is located for 15-SEP-2020.' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 21:03:46
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
Query 'CRA cannot locate in Source, where Temperature is located for 15-SEP-2020.' answered with 'Updated, per source.' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 02:00:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 02:00:41

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

Temperature

Audit	User	Time (GMT)
User opened query 'CRA cannot locate in Source, where Temperature is located for 15-SEP-2020.' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 00:26:05
User entered '99.0' F	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:22

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
User closed query 'Per Source, "Chills = Moderate". Please re-confirm with Source and update severity. ' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 17:45:09
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 17:45:08
Query 'Per Source, "Chills = Moderate". Please re-confirm with Source and update severity. ' answered by data change (Site from CRA).	System	16 Mar 2021 23:13:17
Signature has been broken.	(b) (4), (b) (6)	16 Mar 2021 23:13:17
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 23:13:17
User opened query 'Per Source, "Chills = Moderate". Please re-confirm with Source and update severity. ' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 21:07:35
User closed query 'CRA cannot locate in Source, Where "Chills" are noted for 15-SEP-2020.' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 21:06:17
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 02:03:54
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 02:02:41
Query 'CRA cannot locate in Source, Where "Chills" are noted for 15-SEP-2020.' answered with 'Updated, per source.' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 02:01:01
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 02:00:41
User opened query 'CRA cannot locate in Source, Where "Chills" are noted for 15-SEP-2020.' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 00:28:43
User entered 'Mild (Mild)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:22

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:07:45
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:22

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:07:47
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:22

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:07:50
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:22

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (16)
Generated On: 12 Aug 2021 13:21:23
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
User closed query 'Per Source, " Fatigue = Moderate". Please re-confirm with Source and update severity. ' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 17:45:15
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 17:45:13
Query 'Per Source, " Fatigue = Moderate". Please re-confirm with Source and update severity. ' answered by data change (Site from CRA).	System	16 Mar 2021 23:13:17
Signature has been broken.	(b) (4), (b) (6)	16 Mar 2021 23:13:17
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 23:13:17
User opened query 'Per Source, " Fatigue = Moderate". Please re-confirm with Source and update severity. ' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 21:08:38
DataPoint Un-verified.	(b) (4), (b) (6)	09 Mar 2021 21:07:58
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 00:28:58
User entered 'Mild (Mild)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:22

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
User closed query 'Per Source, '' Muscle Aches = Moderate''. Please re-confirm with Source and update severity.' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 17:45:19
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 17:45:17
Query 'Per Source, '' Muscle Aches = Moderate''. Please re-confirm with Source and update severity.' answered by data change (Site from CRA).	System	16 Mar 2021 23:13:17
Signature has been broken.	(b) (4), (b) (6)	16 Mar 2021 23:13:17
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 23:13:17
User opened query 'Per Source, '' Muscle Aches = Moderate''. Please re-confirm with Source and update severity.' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 21:09:20
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:22

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:09:26
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:22

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (16)
Generated On: 12 Aug 2021 13:21:23
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:09:29
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:22

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:09:37
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:22

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:09:39
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:22

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:09:43
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:22

FDA-CBER-2022-1614-3091113

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:09:44
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:22

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:09:46
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:22

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:09:50
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:22

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:09:55
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:22

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:21:23

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:09:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:22

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 02:03:54
User entered 'Day 2 (Day 2)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:57

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:10:16
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered '16 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:57

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:10:17
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered '0'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:57

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:10:19
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered missing code ND - Not Done.	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:57

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered '%'	System	25 Nov 2020 19:26:57

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:21:02
User closed query 'Subject reported "Fever" starting on 14-SEP-2020 (99F)"; however, we should see Fever/Temperature of "99 F" until the Subject comes into the Site on 18-SEP-2020. Please update Temperature for Day 3 - 16/SEP/2020.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 23:21:01
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Query 'Subject reported "Fever" starting on 14-SEP-2020 (99F)"; however, we should see Fever/Temperature of "99 F" until the Subject comes into the Site on 18-SEP-2020. Please update Temperature for Day 3 - 16/SEP/2020.' answered by data change (Site from CRA).	System	16 Mar 2021 22:57:33
Signature has been broken.	(b) (4), (b) (6)	16 Mar 2021 22:57:33
User entered '99.0' F reason for change: Per Query Resolution	(b) (4), (b) (6)	16 Mar 2021 22:57:33
User opened query 'Subject reported "Fever" starting on 14-SEP-2020 (99F)"; however, we should see Fever/Temperature of "99 F" until the Subject comes into the Site on 18-SEP-2020. Please update Temperature for Day 3 - 16/SEP/2020.' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 21:10:42
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 02:03:54
User entered '99.0' F	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:57

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (17)
Generated On: 12 Aug 2021 13:21:23
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
User closed query 'Per Source, "Chills = Moderate". Please re-confirm with Source and update severity.' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 17:45:28
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 17:45:26
Query 'Per Source, "Chills = Moderate". Please re-confirm with Source and update severity.' answered by data change (Site from CRA).	System	16 Mar 2021 23:13:54
Signature has been broken.	(b) (4), (b) (6)	16 Mar 2021 23:13:54
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 23:13:54
User opened query 'Per Source, "Chills = Moderate". Please re-confirm with Source and update severity.' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 21:11:31
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'Mild (Mild)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:57

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:11:45
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:57

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:11:48
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:57

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:11:53
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:57

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
User closed query 'Per Source, " Fatigue = Moderate". Please re-confirm with Source and update severity.' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 17:45:34
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 17:45:32
Query 'Per Source, " Fatigue = Moderate". Please re-confirm with Source and update severity.' answered by data change (Site from CRA).	System	16 Mar 2021 23:13:54
Signature has been broken.	(b) (4), (b) (6)	16 Mar 2021 23:13:54
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 23:13:54
User opened query 'Per Source, " Fatigue = Moderate". Please re-confirm with Source and update severity.' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 21:12:31
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'Mild (Mild)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:57

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
User closed query 'Per Source, "Muscle Aches = Moderate". Please re-confirm with Source and update severity. ' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 17:45:37
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 17:45:35
Query 'Per Source, "Muscle Aches = Moderate". Please re-confirm with Source and update severity. ' answered by data change (Site from CRA).	System	16 Mar 2021 23:13:54
Signature has been broken.	(b) (4), (b) (6)	16 Mar 2021 23:13:54
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 23:13:54
User opened query 'Per Source, "Muscle Aches = Moderate". Please re-confirm with Source and update severity. ' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 21:13:37
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:57

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:14:48
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:57

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:14:52
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:57

FDA-CBER-2022-1614-3091132

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:14:54
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:57

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:14:56
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:57

Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (17)
Generated On: 12 Aug 2021 13:21:23

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:14:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:57

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:15:32
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:57

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (17)
Generated On: 12 Aug 2021 13:21:23
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:15:33
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:57

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:15:35
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:57

FDA-CBER-2022-1614-3091138

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:15:38
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:57

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:21:23

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:15:40
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)' reason for change: Data Entry Error	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:27:09
User entered empty.	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:26:57

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 02:04:38
User entered 'Day 3 (Day 3)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:27:47

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (18)
Generated On: 12 Aug 2021 13:21:23
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:16:03
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered '17 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:27:47

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:16:05
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered '0'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:27:47

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:16:18
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered missing code ND - Not Done.	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:27:47

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (18)
Generated On: 12 Aug 2021 13:21:23
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered '%'	System	25 Nov 2020 19:27:47

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:21:09
User closed query 'Subject reported "Fever" starting on 14-SEP-2020 (99F)"; however, we should see Fever/Temperature of "99 F" until the Subject comes into the Site on 18-SEP-2020. Please update Temperature for Day 4 - 17/SEP/2020.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 23:21:08
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
Query 'Subject reported "Fever" starting on 14-SEP-2020 (99F)"; however, we should see Fever/Temperature of "99 F" until the Subject comes into the Site on 18-SEP-2020. Please update Temperature for Day 4 - 17/SEP/2020.' answered by data change (Site from CRA).	System	16 Mar 2021 22:57:57
Signature has been broken.	(b) (4), (b) (6)	16 Mar 2021 22:57:57
User entered '99.0' F reason for change: Per Query Resolution	(b) (4), (b) (6)	16 Mar 2021 22:57:57
User opened query 'Subject reported "Fever" starting on 14-SEP-2020 (99F)"; however, we should see Fever/Temperature of "99 F" until the Subject comes into the Site on 18-SEP-2020. Please update Temperature for Day 4 - 17/SEP/2020.' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 21:16:29
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 02:04:38
User entered '99.0' F	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:27:47

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (18)
Generated On: 12 Aug 2021 13:21:23
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
User closed query 'Per Source, "Chills = Moderate". Please re-confirm with Source and update severity. ' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 17:45:44
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 17:45:42
Query 'Per Source, "Chills = Moderate". Please re-confirm with Source and update severity. ' answered by data change (Site from CRA).	System	16 Mar 2021 23:14:28
Signature has been broken.	(b) (4), (b) (6)	16 Mar 2021 23:14:28
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 23:14:28
User opened query 'Per Source, "Chills = Moderate". Please re-confirm with Source and update severity. ' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 21:17:15
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'Mild (Mild)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:27:47

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:17:20
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:27:47

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:18:12
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:27:47

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:18:17
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:27:47

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
User closed query 'Per Source, "Fatigue = Moderate" Please re-confirm with Source and update severity.' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 17:45:49
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 17:45:47
Query 'Per Source, "Fatigue = Moderate". Please re-confirm with Source and update severity.' answered by data change (Site from CRA).	System	16 Mar 2021 23:14:28
Signature has been broken.	(b) (4), (b) (6)	16 Mar 2021 23:14:28
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 23:14:28
User opened query 'Per Source, "Fatigue = Moderate". Please re-confirm with Source and update severity.' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 21:18:55
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'Mild (Mild)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:27:47

Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (18)
Generated On: 12 Aug 2021 13:21:23

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:05:06
User closed query 'Per Source, "Muscle Aches = Moderate". Please re-confirm with Source and update severity. ' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 17:45:54
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 17:45:52
Query 'Per Source, "Muscle Aches = Moderate". Please re-confirm with Source and update severity. ' answered by data change (Site from CRA).	System	16 Mar 2021 23:14:28
Signature has been broken.	(b) (4), (b) (6)	16 Mar 2021 23:14:28
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 23:14:28
User opened query 'Per Source, "Muscle Aches = Moderate". Please re-confirm with Source and update severity. ' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 21:20:05
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:27:47

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:20:11
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:27:47

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (18)
Generated On: 12 Aug 2021 13:21:23
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:20:12
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:27:47

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:20:16
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:27:47

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:20:18
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:27:47

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:20:19
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:27:47

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:20:21
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:27:47

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:22:30
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:27:47

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:22:33
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:27:47

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:22:35
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:27:47

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:21:23

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:22:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	Lauren Arnett (b) (4) (b) (4)	25 Nov 2020 19:27:47

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:21:23

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	23 Feb 2021 17:28:02

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (19)
Generated On: 12 Aug 2021 13:21:23
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:55:21
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered '14 Sep 2020'	(b) (4), (b) (6)	23 Feb 2021 17:28:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:21:23

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:55:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered '0'	(b) (4), (b) (6)	23 Feb 2021 17:28:02

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:55:25
User signature succeeded.	Scott Overcash (b) (4), (b) (4)	25 Feb 2021 01:48:31
User entered missing code ND - Not Done.	(b) (4), (b) (6)	23 Feb 2021 17:28:02

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (19)
Generated On: 12 Aug 2021 13:21:23
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered '%'	System	23 Feb 2021 17:28:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:21:23

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:58:11
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered '99.0' F	(b) (4), (b) (6)	23 Feb 2021 17:28:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:21:23

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:58:20
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	23 Feb 2021 17:28:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:21:23

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:01:02
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	(b) (4), (b) (6)	23 Feb 2021 17:28:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:21:23

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:01:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	(b) (4), (b) (6)	23 Feb 2021 17:28:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:21:23

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:01:38
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	(b) (4), (b) (6)	23 Feb 2021 17:28:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:21:23

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 20:58:43
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	23 Feb 2021 17:28:02

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (19)
Generated On: 12 Aug 2021 13:21:23
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:05:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:46:15
DataPoint Un-verified.		16 Mar 2021 23:12:04
Signature has been broken.		16 Mar 2021 23:12:04
User entered 'Moderate (Moderate)' reason for change: Per Query Resolution		16 Mar 2021 23:12:04
DataPoint Verified.		09 Mar 2021 21:00:38
Query 'Per Source, "Muscle Aches = Moderate". Please re-confirm with Source and update Symptom.' canceled (Site from CRA).		09 Mar 2021 21:00:17
User opened query 'Per Source, "Muscle Aches = Moderate". Please re-confirm with Source and update Symptom.' (Site from CRA).		09 Mar 2021 21:00:09
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 17:28:02

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (19)
Generated On: 12 Aug 2021 13:21:23

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	28 Apr 2021 22:21:44
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:32:44
User closed query ' Per Source, "Muscle Aches = Moderate". Please re-confirm with Source and update Symptom. The Update Was Not Completed' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 01:32:39
Query ' Per Source, "Muscle Aches = Moderate". Please re-confirm with Source and update Symptom. The Update Was Not Completed' answered with 'updated' (Site from CRA).	Gordon Bovee (b) (4) (b) (4)	19 Apr 2021 22:14:18
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Gordon Bovee (b) (4) (b) (4)	19 Apr 2021 22:13:57
Signature has been broken.	Gordon Bovee (b) (4) (b) (4)	19 Apr 2021 22:13:40
User entered 'Mild (Mild)' reason for change: Data Entry Error	Gordon Bovee (b) (4) (b) (4)	19 Apr 2021 22:13:40
User opened query ' Per Source, "Muscle Aches = Moderate". Please re-confirm with Source and update Symptom. The Update Was Not Completed' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 23:21:37
User closed query 'Per Source, "Muscle Aches = Moderate". Please re-confirm with Source and update Symptom.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 23:21:18
Query 'Per Source, "Muscle Aches = Moderate". Please re-confirm with Source and update Symptom.' answered with 'Updated.' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 23:12:13
User opened query 'Per Source, "Muscle Aches = Moderate". Please re-confirm with Source and update Symptom.' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 21:00:28
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:21:23

Body Aches

Audit	User	Time (GMT)
User entered 'None (None)'	(b) (4), (b) (6)	23 Feb 2021 17:28:02

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:00:40
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	(b) (4), (b) (6)	23 Feb 2021 17:28:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:21:23

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:00:42
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	(b) (4), (b) (6)	23 Feb 2021 17:28:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:21:23

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:00:44
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	(b) (4), (b) (6)	23 Feb 2021 17:28:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:21:23

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:00:45
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	(b) (4), (b) (6)	23 Feb 2021 17:28:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:21:23

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:00:47
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	(b) (4), (b) (6)	23 Feb 2021 17:28:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:21:23

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:00:48
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	(b) (4), (b) (6)	23 Feb 2021 17:28:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:21:23

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:00:50
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	(b) (4), (b) (6)	23 Feb 2021 17:28:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:21:23

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:00:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	(b) (4), (b) (6)	23 Feb 2021 17:28:02

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Symptom Log (19)
Generated On: 12 Aug 2021 13:21:23
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:29:41
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:00:53
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'None (None)'	(b) (4), (b) (6)	23 Feb 2021 17:28:02

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:21:23

Date of Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:36:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:36:31
User entered '18 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 01:20:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:21:23

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:36:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 01:20:24

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:36:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:08:29
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'Correct as is. Please previously reported AE of Symptomatic COVID-19' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 03:28:04
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:31
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	23 Sep 2020 01:20:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 01:20:24

FDA-CBER-2022-1614-3091188

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: COVID Diagnostic Test
Generated On: 12 Aug 2021 13:21:23
Date of Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:36:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:36:31
User entered '18 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 01:20:24

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:36:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:36:31
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	23 Sep 2020 01:20:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:21:23

Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:36:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:31
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 01:20:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:21:23

Was this diagnostic test performed at a lab other than the Study Central Lab?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:36:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:31
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 01:20:24

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: COVID Diagnostic Test
Generated On: 12 Aug 2021 13:21:23
Lab/ Institution Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:36:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:31
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 01:20:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:21:23

CLIA Certified?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:36:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:31
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 01:20:24

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:21:23

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:36:58
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered '1'	System	23 Sep 2020 01:20:24

Folder: Covid-19 Assessment 18 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 12 Aug 2021 13:21:23

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 12 Aug 2021 13:21:23
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 12 Aug 2021 13:21:23
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

Respiratory Rate

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

Did the subject have Heart Rate ≥ 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:36:58
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:17:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 19:17:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:17:48
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:16:43
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 12 Aug 2021 13:21:23
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 12 Aug 2021 13:21:23
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 12 Aug 2021 13:21:23
Heart Rate

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:17:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 19:17:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:17:48
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:16:43
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 12 Aug 2021 13:21:23
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 12 Aug 2021 13:21:23
Oxygen Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:17:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 19:17:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:17:48
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:16:43
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 12 Aug 2021 13:21:23
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

Folder: Covid-19 Assessment 18 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 12 Aug 2021 13:21:23
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 12 Aug 2021 13:21:23

PaO2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:17:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 19:17:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:17:48
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:16:43
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 12 Aug 2021 13:21:23
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:17:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 19:17:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:17:48
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:16:43
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

FDA-CBER-2022-1614-3091214

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 12 Aug 2021 13:21:23
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

High-Flow Oxygen?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 12 Aug 2021 13:21:23
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

Non-Invasive Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 12 Aug 2021 13:21:23

Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 12 Aug 2021 13:21:23
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 12 Aug 2021 13:21:23
Mechanical Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 12 Aug 2021 13:21:23
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 12 Aug 2021 13:21:23
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

ECMO?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 12 Aug 2021 13:21:23
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 12 Aug 2021 13:21:23
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

Folder: Covid-19 Assessment 18 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 12 Aug 2021 13:21:23
Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:46:46
User closed query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and provide responses.' (Site from DM).		28 Jan 2021 20:00:52
Query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and provide responses.' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 23:54:45
DataPoint Un-verified.	(b) (4), (b) (6)	26 Jan 2021 23:54:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 23:54:23
User opened query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and provide responses.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 04:46:13
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

FDA-CBER-2022-1614-3091228

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 12 Aug 2021 13:21:23
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 12 Aug 2021 13:21:23
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

Evidence of Shock Requires
Vasopressors

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 12 Aug 2021 13:21:23
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

FDA-CBER-2022-1614-3091233

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

Acute Renal Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

Hepatic Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

FDA-CBER-2022-1614-3091236

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

Neurologic Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

FDA-CBER-2022-1614-3091238

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 12 Aug 2021 13:21:23
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 12 Aug 2021 13:21:23
Clinical Evidence

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 19:47:10
DataPoint Un-verified.		26 Jan 2021 23:54:23
User entered 'No (N)' reason for change: Data Entry Error		26 Jan 2021 23:54:23
DataPoint Verified.		20 Oct 2020 23:36:58
User entered empty.		07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

Date of Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

Radiographical Evidence

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 12 Aug 2021 13:21:23
Date of Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.		07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

Admission to an intensive care unit due to SARS-CoV-2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:36:58
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:17:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 19:17:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:17:48
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:16:43
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207

Folder: Covid-19 Assessment 18 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:21:23

Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Covid-19 Severity Assessment
Generated On: 12 Aug 2021 13:21:23
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:06
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:36:58
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:16:43

US3732207
Folder: Covid-19 Assessment 18 Sep 2020
Form: Generate Next COVID-19 Assessment
Generated On: 12 Aug 2021 13:21:23
Generate Next COVID-19 Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:27
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 12:37:12
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:23:28
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User entered 'No (N)'	(b) (4), (b) (6)	28 Jan 2021 23:51:55

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:21:23

Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:21:23

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:39:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:21:23

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:39:00
User entered '20 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 21:01:32

FDA-CBER-2022-1614-3091250

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:21:23

Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:21:23

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:39:00
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:21:23

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:39:00
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:21:23

Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:21:23

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:39:00
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 00:35:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 00:35:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 00:35:25
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 21:01:32
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:01:32

FDA-CBER-2022-1614-3091255

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:21:23

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:39:00
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:21:23

Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:21:23

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:39:00
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 00:35:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 00:35:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 00:35:25
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 21:01:32
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:01:32

FDA-CBER-2022-1614-3091258

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:21:23

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:39:00
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:01:32

FDA-CBER-2022-1614-3091259

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:21:23

Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:21:23

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:39:00
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 00:35:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 00:35:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 00:35:25
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 21:01:32
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:21:23

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:39:00
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:21:23

Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:21:23

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:39:00
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 00:35:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 00:35:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 00:35:25
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 21:01:32
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:21:23

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:39:00
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:21:23

Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	24 Sep 2020 21:01:32

FDA-CBER-2022-1614-3091266

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:21:23

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:39:00
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 00:35:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 00:35:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 00:35:25
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 21:01:32
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:01:32

FDA-CBER-2022-1614-3091267

US3732207

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:21:23

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:39:00
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:01:32

US3732207
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 12 Aug 2021 13:21:23
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:38:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 01:21:57

US3732207

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:38:19
User entered '18 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 01:21:57

US3732207

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:38:19
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	23 Sep 2020 01:21:57

US3732207
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 12 Aug 2021 13:21:23
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered 'SICKD1'	System	23 Sep 2020 01:21:57

US3732207
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 12 Aug 2021 13:21:23
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:41:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 01:22:45

US3732207

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:41:49
User entered '18 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 01:22:45

FDA-CBER-2022-1614-3091274

Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:41:49
User entered '13:19'	(b) (4), (b) (6)	23 Sep 2020 01:22:45

FDA-CBER-2022-1614-3091275

US3732207

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered '18 Sep 2020 13:19'	System	23 Sep 2020 01:22:45

US3732207
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 12 Aug 2021 13:21:23

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:41:49
User entered '178.5' cm	(b) (4), (b) (6)	23 Sep 2020 01:22:45
DataPoint set to visible.	System	23 Sep 2020 01:21:57

US3732207

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:41:49
User entered '211.9' lb	(b) (4), (b) (6)	23 Sep 2020 01:22:45
DataPoint set to visible.	System	23 Sep 2020 01:21:57

US3732207
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 12 Aug 2021 13:21:23
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:41:49
User entered '97.5' F	(b) (4), (b) (6)	23 Sep 2020 01:22:45

US3732207

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:41:49
User entered 'Oral (Oral)'	(b) (4), (b) (6)	23 Sep 2020 01:22:45

US3732207
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 12 Aug 2021 13:21:23
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:41:49
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 01:22:45

US3732207
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 12 Aug 2021 13:21:23
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:41:49
User entered '63'	(b) (4), (b) (6)	23 Sep 2020 01:22:45

US3732207
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 12 Aug 2021 13:21:23
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered 'bpm'	System	23 Sep 2020 01:22:45

US3732207
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 12 Aug 2021 13:21:23

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:41:49
User entered '18'	(b) (4), (b) (6)	23 Sep 2020 01:22:45

US3732207
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 12 Aug 2021 13:21:23
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered 'breaths/min'	System	23 Sep 2020 01:22:45

US3732207

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:41:49
User entered '135'	(b) (4), (b) (6)	23 Sep 2020 01:22:45

US3732207
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 12 Aug 2021 13:21:23
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered 'mmHg'	System	23 Sep 2020 01:22:45

US3732207

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:41:49
User entered '85'	(b) (4), (b) (6)	23 Sep 2020 01:22:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered 'mmHg'	System	23 Sep 2020 01:22:45

FDA-CBER-2022-1614-3091289

US3732207

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57

US3732207

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:41:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 01:23:02

FDA-CBER-2022-1614-3091292

Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 12 Aug 2021 13:21:23
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:41:57
User entered '18 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 01:23:02

US3732207

Folder: Illness Visit Day 1 (1)

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

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:42:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 01:23:10

FDA-CBER-2022-1614-3091294

US3732207

Folder: Illness Visit Day 1 (1)

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

Generated On: 12 Aug 2021 13:21:23

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 23:42:38
User entered '18 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 01:23:10

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:43:18
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 00:34:19

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:43:18
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:34:19

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 23:43:18
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:34:19

US3732207
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 12 Aug 2021 13:21:23
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered 'SICKD28'	System	15 Oct 2020 00:34:19

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:33:54
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 00:34:28

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:33:54
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:34:28

US3732207
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 12 Aug 2021 13:21:23
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:33:54
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:34:28

FDA-CBER-2022-1614-3091302

US3732207
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 12 Aug 2021 13:21:23

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered empty.	System	15 Oct 2020 00:34:28

US3732207
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 12 Aug 2021 13:21:23
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:33:54
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:34:28

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:33:54
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:34:28

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:33:54
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:34:28

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:33:54
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:34:28

US3732207
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 12 Aug 2021 13:21:23
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered empty.	System	15 Oct 2020 00:34:28

US3732207
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 12 Aug 2021 13:21:23
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:33:54
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:34:28

US3732207
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 12 Aug 2021 13:21:23
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered empty.	System	15 Oct 2020 00:34:28

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:33:54
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:34:28

FDA-CBER-2022-1614-3091311

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered empty.	System	15 Oct 2020 00:34:28

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:33:54
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:34:28

US3732207
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 12 Aug 2021 13:21:23
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered empty.	System	15 Oct 2020 00:34:28

US3732207
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 12 Aug 2021 13:21:23
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57

US3732207
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 12 Aug 2021 13:21:23
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:34:13
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 00:34:33

US3732207

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:34:13
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:34:33

US3732207

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:34:20
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 00:34:45

US3732207

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 12 Aug 2021 13:21:23

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:34:20
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:34:45

US3732207

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:21:23

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:03:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 22:57:30

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:10:49
User entered 'USA-US102-2020-mRNA-1273-P301000002'	System	23 Sep 2020 16:10:35
User entered 'New'	(b) (4), (b) (6)	23 Sep 2020 16:10:35

US3732207
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 12 Aug 2021 13:21:23
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:38:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:38:20
Data point term sent to Coder	System	23 Nov 2020 20:59:25
Query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. ' canceled (Site from System).	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:59:05
User opened query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. ' (Site from System).	Coder Import (b) (4) (b) (4)	23 Nov 2020 12:23:58
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, AE is not the reason for discontinuation. Please reconcile with End of Study/Discontinuation eCRF page and update applicable details accordingly. Otherwise, clarify.' canceled (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 23:21:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, AE is not the reason for discontinuation. Please reconcile with End of Study/Discontinuation eCRF page and update applicable details accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 19:45:33

US3732207
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 12 Aug 2021 13:21:23
Adverse event

Audit	User	Time (GMT)
User closed query 'PV Query: Event term is reported as 'Symptomatic COVID-19', however, subject had no symptoms. Please consider updating event term to 'Positive COVID-19 PCR', or provide subject's signs/symptoms associated with COVID-19 infection.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:47:01
User closed query 'PV Query: Please complete the Covid-19 Assessments tab, including symptoms log and severity assessment. ' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:46:58
Query 'PV Query: Event term is reported as 'Symptomatic COVID-19', however, subject had no symptoms. Please consider updating event term to 'Positive COVID-19 PCR', or provide subject's signs/symptoms associated with COVID-19 infection.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 19:04:13
Query 'PV Query: Please complete the Covid-19 Assessments tab, including symptoms log and severity assessment. ' answered with 'subject decided to withdraw from study.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 19:03:56
User opened query 'PV Query: Event term is reported as 'Symptomatic COVID-19', however, subject had no symptoms. Please consider updating event term to 'Positive COVID-19 PCR', or provide subject's signs/symptoms associated with COVID-19 infection.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 15:10:26
User opened query 'PV Query: Please complete the Covid-19 Assessments tab, including symptoms log and severity assessment. ' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 15:08:13
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 23:10:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 23:10:42
Data point term sent to Coder	System	22 Sep 2020 23:09:38
User entered 'Symptomatic COVID-19'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:26:02
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Un-verified.	(b) (4), (b) (6)	24 Feb 2021 02:12:56
User entered '14 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 02:12:56
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered '15 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:31
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	22 Sep 2020 23:09:00
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Sep 2020 23:09:00
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 23:09:00
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Sep 2020 23:08:39
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	22 Sep 2020 23:08:39
User entered 'un:un' (non-conformant).	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered empty.	System	22 Sep 2020 23:09:00
User entered '15 Sep 2020 UN:UN' (non-conformant).	System	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

FDA-CBER-2022-1614-3091331

US3732207
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 12 Aug 2021 13:21:23
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:47:16
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'end date will not be captured. subject decided to withdraw from study. no further contact will be made' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 19:13:26
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 15:08:42
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:08:39

FDA-CBER-2022-1614-3091333

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered empty.	System	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 12 Aug 2021 13:21:23
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	25 Sep 2020 13:29:40
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	22 Sep 2020 23:08:39
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	25 Nov 2020 06:01:17
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'data entered is correct as is, AE of symptomatic COVID is reason why subject decided to withdraw from study. Site was queried to updated reason for discontinuation to "Due to SARS-CoV-2" in End of Study folder. Please advise if SARS-CoV-2 should have been selected, or if AE was correct the first time' (Site from System).	Lauren Arnett (b) (4) (b) (4)	24 Nov 2020 20:21:08
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	24 Nov 2020 20:14:48
Query 'Per CDM: Dose discontinuation form is has not be completed. Please reconcile. ' canceled (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:31:15
User opened query 'Per CDM: Dose discontinuation form is has not be completed. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:27:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 12 Aug 2021 13:21:23
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 06:27:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 03:26:38
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 03:26:38
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' canceled (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:09:33
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 10:10:36
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered '1'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 12 Aug 2021 13:21:23
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:27:59
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 03:26:38
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 03:26:38
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 12 Aug 2021 13:21:23
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:31
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:47:22
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'unknown has been selected due to subject withdrawing from participation' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 19:14:42
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:14:16
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 15:09:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 08:53:39
Query 'Data is required. Please complete.' answered with 'will be updated upon final outcome' (Site from System).	(b) (4), (b) (6)	22 Sep 2020 23:09:35
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 23:08:39
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:04:31
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:08:39

US3732207
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 12 Aug 2021 13:21:23
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:04:31
User closed query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:47:32
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:47:29
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)	08 Oct 2020 13:47:25
Query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' answered with 'confirmed as no ' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 19:16:26
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 19:16:11
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'no safety blood work obtained. Just central PCR as positive' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 19:15:41
User opened query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 15:10:42

US3732207
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 12 Aug 2021 13:21:23
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 15:09:30
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)	29 Sep 2020 15:09:00
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 23:08:39

FDA-CBER-2022-1614-3091356

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered '0'	System	22 Sep 2020 23:08:39

US3732207

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered '1'	System	22 Sep 2020 23:08:39

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:30
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	01 Sep 2020 00:58:29

FDA-CBER-2022-1614-3091360

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:10:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: CALCITONIN GENE-RELATED PEPTIDE (CGRP) ANTAGONISTS, PRODUCT: ERENUMAB, PRODUCTSYNONYM: AIMOVIG [ERENUMAB] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 02:44:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 02:44:37
Data point term sent to Coder	System	01 Sep 2020 00:59:40
User entered 'aimavig'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:59:36

FDA-CBER-2022-1614-3091361

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'migraine headaches'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered '70'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:59:36

FDA-CBER-2022-1614-3091364

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'every month (QM)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'Subcutaneous (SUBCUTANEOUS)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered empty.	Lauren Arnett (b) (4)	01 Sep 2020 00:59:36
	(b) (4)	

FDA-CBER-2022-1614-3091370

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'un UNK 2008'	Lauren Arnett (b) (4)	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered '0'	Lauren Arnett (b) (4)	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered empty.	Lauren Arnett (b) (4)	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered '1'	System	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered '1'	System	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered '802 (802)'	System	01 Sep 2020 00:59:36

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM, PRODUCTSYNONYM: ATIVAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 01:01:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 01:01:40
Data point term sent to Coder	System	01 Sep 2020 01:00:43
User entered 'ativan'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 01:00:37

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 01:00:37

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'anxiety'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 01:00:37

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered '1'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 01:00:37

FDA-CBER-2022-1614-3091382

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 01:00:37

FDA-CBER-2022-1614-3091383

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 01:00:37

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'as needed (PRN)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 01:00:37

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 01:00:37

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 01:00:37

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 01:00:37

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'un UNK 2010'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 01:00:37

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered '0'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 01:00:37

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 01:00:37

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered empty.	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 01:00:37

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	01 Sep 2020 01:00:37

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered empty.	System	01 Sep 2020 01:00:37

FDA-CBER-2022-1614-3091394

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered empty.	System	01 Sep 2020 01:00:37

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered empty.	System	01 Sep 2020 01:00:37

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 04:13:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 04:13:40
Data point term sent to Coder	System	30 Sep 2020 21:21:55
User entered 'ADVIL'	(b) (4), (b) (6)	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'SYMPTOMATIC COVID-19'	(b) (4), (b) (6)	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered '800'	(b) (4), (b) (6)	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'mg (mg)'	(b) (4), (b) (6)	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:21:15

FDA-CBER-2022-1614-3091402

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'other (OTHER)'	(b) (4), (b) (6)	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'EVERY 6 HOURS'	(b) (4), (b) (6)	30 Sep 2020 21:21:15

FDA-CBER-2022-1614-3091404

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered '15 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 21:21:15

FDA-CBER-2022-1614-3091409

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:08:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:28:30
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 03:23:49
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 03:23:44
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 03:23:44
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 10:09:48
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered empty.	System	30 Sep 2020 21:21:15

FDA-CBER-2022-1614-3091412

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered empty.	System	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered empty.	System	30 Sep 2020 21:21:15

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:10:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 21:23:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 21:23:45
Data point term sent to Coder	System	30 Sep 2020 21:22:56
User entered 'ACETAMINOPHEN'	(b) (4), (b) (6)	30 Sep 2020 21:22:52

FDA-CBER-2022-1614-3091415

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'No (N)'	(b) (4), (b) (6)	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:31
User closed query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:08:51
Query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' answered with 'updated AE' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 03:26:55
User opened query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:19:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'SYMPTOMATIC COVID-19'	(b) (4), (b) (6)	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered '1000'	(b) (4), (b) (6)	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'mg (mg)'	(b) (4), (b) (6)	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'other (OTHER)'	(b) (4), (b) (6)	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'EVERY 6 HOURS'	(b) (4), (b) (6)	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered '17 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered '0'	(b) (4), (b) (6)	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 21:22:52

FDA-CBER-2022-1614-3091427

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 21:22:52

FDA-CBER-2022-1614-3091428

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:00:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:28:54
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 03:27:31
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 03:27:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 03:27:26
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 10:10:10
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 21:22:52

FDA-CBER-2022-1614-3091429

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered empty.	System	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered empty.	System	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User entered empty.	System	30 Sep 2020 21:22:52

US3732207

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:21:23

Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:10:15
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 19:15:50

FDA-CBER-2022-1614-3091433

US3732207

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:21:23

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:14:16
User entered '21 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 21:23:02

US3732207

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:21:23

Primary reason for dosing discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:50:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
User closed query 'Per CDM: Please consider selecting 'Due to SARS-CoV-2' and make all appropriate updates' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 05:04:56
Query 'Per CDM: Please consider selecting 'Due to SARS-CoV-2' and make all appropriate updates' answered with 'updated, please note it was subjects decision to withdraw from study due to positive COVID' (Site from DM).	Lauren Arnett (b) (4) (b) (4)	24 Nov 2020 20:15:41
DataPoint Un-verified.	Lauren Arnett (b) (4) (b) (4)	24 Nov 2020 20:14:48
User entered 'Due to SARS-COV-2 (COVID)' reason for change: Data Entry Error	Lauren Arnett (b) (4) (b) (4)	24 Nov 2020 20:14:48
User opened query 'Per CDM: Please consider selecting 'Due to SARS-CoV-2' and make all appropriate updates' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:44:48
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:14:16
User entered 'AE (specify) (ADVERSE EVENT)'	(b) (4), (b) (6)	24 Sep 2020 21:23:02

US3732207

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:50:06
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	24 Nov 2020 20:14:57
DataPoint Un-verified.	Lauren Arnett (b) (4) (b) (4)	24 Nov 2020 20:14:57
User entered empty; reason for change New Information	Lauren Arnett (b) (4) (b) (4)	24 Nov 2020 20:14:57
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	24 Nov 2020 20:14:48
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:14:16
User entered 'Symptomatic COVID-19'	(b) (4), (b) (6)	24 Sep 2020 21:23:02

US3732207

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:21:23

Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:14:31
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 21:25:04

US3732207
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 12 Aug 2021 13:21:23

Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:14:31
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	(b) (4), (b) (6)	24 Sep 2020 21:25:04

US3732207

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:14:31
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	24 Sep 2020 21:27:00
User entered 'Subject no longer wants to participate due to too many follow-up calls/visits (since they are confirmed COVID positive)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 21:27:00
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	24 Sep 2020 21:25:04
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:25:04

US3732207

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:21:23

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:14:31
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:25:04

US3732207
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 12 Aug 2021 13:21:23
If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:14:31
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:25:04

US3732207

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:21:23

Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:14:31
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:25:04

US3732207
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 12 Aug 2021 13:21:23
Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:14:31
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:25:04

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'USA-US102-2020-MRNA-1273-P301000002'	System	23 Sep 2020 16:10:35

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

FDA-CBER-2022-1614-3091451

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'Scott'	System	23 Sep 2020 16:10:35

FDA-CBER-2022-1614-3091452

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'Overcash'	System	23 Sep 2020 16:10:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered '5565 Grossmont Center Dr'	System	23 Sep 2020 16:10:35

FDA-CBER-2022-1614-3091454

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'La Mesa'	System	23 Sep 2020 16:10:35

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'CA'	System	23 Sep 2020 16:10:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered '91942'	System	23 Sep 2020 16:10:35

FDA-CBER-2022-1614-3091457

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:47:47
User entered 'US'	System	23 Sep 2020 16:11:15

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	26 Feb 2021 01:55:45
Signature has been broken.	System	25 Feb 2021 20:43:16
User entered '3'	System	25 Feb 2021 20:43:16
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
User entered '2'	System	08 Oct 2020 13:47:58
User entered '1'	System	23 Sep 2020 16:11:15

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'USA-US102-2020-MRNA-1273-P301000002'	System	23 Sep 2020 16:10:35

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

FDA-CBER-2022-1614-3091461

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

FDA-CBER-2022-1614-3091464

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

FDA-CBER-2022-1614-3091465

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'Scott'	System	23 Sep 2020 16:10:35

FDA-CBER-2022-1614-3091468

Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'Overcash'	System	23 Sep 2020 16:10:35

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered '5565 Grossmont Center Dr'	System	23 Sep 2020 16:10:35

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'La Mesa'	System	23 Sep 2020 16:10:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'CA'	System	23 Sep 2020 16:10:35

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered '91942'	System	23 Sep 2020 16:10:35

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:47:47
User entered 'US'	System	23 Sep 2020 16:11:15

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	26 Feb 2021 01:55:45
Signature has been broken.	System	25 Feb 2021 20:43:16
User entered '3'	System	25 Feb 2021 20:43:16
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
User entered '2'	System	08 Oct 2020 13:47:58
User entered '1'	System	23 Sep 2020 16:11:15

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form (1)
Generated On: 12 Aug 2021 13:21:23
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
User entered '23/Sep/2020 12:11'	System	23 Sep 2020 16:11:15

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 12 Aug 2021 13:21:23

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:47:47
User entered '1'	(b) (4), (b) (6)	23 Sep 2020 16:11:15

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'USA-US102-2020-MRNA-1273-P301000002'	System	23 Sep 2020 16:10:35

FDA-CBER-2022-1614-3091478

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

FDA-CBER-2022-1614-3091483

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

FDA-CBER-2022-1614-3091484

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:21:23

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

FDA-CBER-2022-1614-3091485

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'Scott'	System	23 Sep 2020 16:10:35

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23

Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'Overcash'	System	23 Sep 2020 16:10:35

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered '5565 Grossmont Center Dr'	System	23 Sep 2020 16:10:35

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'La Mesa'	System	23 Sep 2020 16:10:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'CA'	System	23 Sep 2020 16:10:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered '91942'	System	23 Sep 2020 16:10:35

FDA-CBER-2022-1614-3091491

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:47:47
User entered 'US'	System	23 Sep 2020 16:11:15

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	26 Feb 2021 01:55:45
Signature has been broken.	System	25 Feb 2021 20:43:16
User entered '3'	System	25 Feb 2021 20:43:16
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
User entered '2'	System	08 Oct 2020 13:47:58
User entered '1'	System	23 Sep 2020 16:11:15

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form (2)
Generated On: 12 Aug 2021 13:21:23
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
User entered '08/Oct/2020 13:47'	System	08 Oct 2020 13:47:58

Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form (2)
Generated On: 12 Aug 2021 13:21:23

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 20:43:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
User entered '1'	(b) (4), (b) (6)	08 Oct 2020 13:47:58

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'USA-US102-2020-MRNA-1273-P301000002'	System	23 Sep 2020 16:10:35

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'No (N)'	System	23 Sep 2020 16:10:35

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'Scott'	System	23 Sep 2020 16:10:35

FDA-CBER-2022-1614-3091504

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'Overcash'	System	23 Sep 2020 16:10:35

FDA-CBER-2022-1614-3091505

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered '5565 Grossmont Center Dr'	System	23 Sep 2020 16:10:35

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'La Mesa'	System	23 Sep 2020 16:10:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered 'CA'	System	23 Sep 2020 16:10:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 16:11:08
User entered '91942'	System	23 Sep 2020 16:10:35

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:58
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:47:47
User entered 'US'	System	23 Sep 2020 16:11:15

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 12 Aug 2021 13:21:23
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	26 Feb 2021 01:55:45
Signature has been broken.	System	25 Feb 2021 20:43:16
User entered '3'	System	25 Feb 2021 20:43:16
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 01:48:39
User entered '2'	System	08 Oct 2020 13:47:58
User entered '1'	System	23 Sep 2020 16:11:15

US3732207
Folder: SAE USA-US102-2020-MRNA-1273-P301000002
Form: Safety Report Form (3)
Generated On: 12 Aug 2021 13:21:23
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:33:06
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	26 Feb 2021 01:55:45
User entered '25/Feb/2021 15:43'	System	25 Feb 2021 20:43:16

US3732207

Folder: SAE USA-US102-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 12 Aug 2021 13:21:23

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 17:57:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 01:33:06
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	26 Feb 2021 01:55:45
User entered '1'	(b) (4), (b) (6)	25 Feb 2021 20:43:16