

US3572251 (Prod: Laguna Clinical Research Associates)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:20:40

All time stamps listed in this document are displayed in GMT

US3572251

Form: Participant Creation

Data signed: (b) (4) 03 Apr 2021 04:56:58

Generated On: 10 Jun 2021 08:20:40

[Participant ID](#)

US3572251

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

US3572251

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Mar 2021 03:41:03

Generated On: 10 Jun 2021 08:20:40

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3572251

Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Mar 2021 03:41:03

Generated On: 10 Jun 2021 08:20:40

Date of Birth (MMM yyyy)	(b) (6) 1978
Age	41
Age Units	YEARS
Age (Derived)	42
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☒ Not Hispanic or Latino ☐ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3572251

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Mar 2021 03:41:03

Generated On: 10 Jun 2021 08:20:40

Date of Informed Consent (<i>dd MMM yyyy</i>)	10 SEP 2020
Month and Year of Informed Consent (derived)	SEP 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

US3572251

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Mar 2021 03:41:03

Generated On: 10 Jun 2021 08:20:40

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3572251

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Mar 2021 03:41:03

Generated On: 10 Jun 2021 08:20:40

Were any significant conditions reported?

Yes ☒

No ☐

US3572251

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 22 Mar 2021 03:41:03

Generated On: 10 Jun 2021 08:20:40

Condition	DIABETES TYPE 2
Start date (dd MMM yyyy)	UN JUL 2020
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)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3572251

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Mar 2021 03:41:03

Generated On: 10 Jun 2021 08:20:40

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN JUL 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)	JUL 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3572251

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Mar 2021 03:41:03

Generated On: 10 Jun 2021 08:20:40

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 12:00
Height (xxx.x)	68 in
Weight (xxx.x)	222 lb
BMI (xxx.x)	33.82556 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	ND - Not Done
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)	

US3572251

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Mar 2021 03:41:03

Generated On: 10 Jun 2021 08:20:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3572251

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Mar 2021 03:41:03

Generated On: 10 Jun 2021 08:20:40

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

US3572251

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Mar 2021 03:41:03

Generated On: 10 Jun 2021 08:20:40

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	

US3572251

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 21 Mar 2021 00:18:35

Generated On: 10 Jun 2021 08:20:40

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3572251

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 21 Mar 2021 00:18:35

Generated On: 10 Jun 2021 08:20:40

What was the date of randomization? (dd MMM yyyy) 10 SEP 2020

What was the participant's randomization number? 146088

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 ☒

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Mar 2021 00:18:35

Generated On: 10 Jun 2021 08:20:40

Height	ND - Not Done
Weight	ND - Not Done

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Mar 2021 00:18:35

Generated On: 10 Jun 2021 08:20:40

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)	10 SEP 2020
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 12:00
Temperature (xxx.x)	97.5 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	102 mmHg
Diastolic Blood Pressure units	MMHG

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Mar 2021 00:18:35

Generated On: 10 Jun 2021 08:20:40

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)	10 SEP 2020
Time of assessment (00:00-23:59)	12:46 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 12:46
Temperature (xxx.x)	97.5 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3572251

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 21 Mar 2021 00:18:35

Generated On: 10 Jun 2021 08:20:40

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.

US3572251

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 21 Mar 2021 00:18:35

Generated On: 10 Jun 2021 08:20:40

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) 10 SEP 2020

What was the treatment time? (00:00-23:59) 12:16 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 12:16

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

US3572251

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Mar 2021 00:18:35

Generated On: 10 Jun 2021 08:20:40

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	10 SEP 2020
Collection time (00:00-23:59)	12:05 (24 HR)
Collection date and time (derived)	10 SEP 2020 12:05

US3572251

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Mar 2021 00:18:35

Generated On: 10 Jun 2021 08:20:40

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:20	10 SEP 2020 12:20
Nasopharyngeal Swab 2	No		

US3572251

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:18:35

Generated On: 10 Jun 2021 08:20:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

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

10 SEP 2020 12:48

PC Open Date & Time

10 SEP 2020 12:36

PC Close Date & Time

10 SEP 2020 15:06

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

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	10 SEP 2020 19:11
PC Open Date & Time	10 SEP 2020 16:01
PC Close Date & Time	11 SEP 2020 11:59

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 12:00

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 12:00

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:40

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 12:04

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:40

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 13:12

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 12:53

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 12:25

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

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

10 SEP 2020 12:49

PC Open Date & Time

10 SEP 2020 12:36

PC Close Date & Time

10 SEP 2020 15:06

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

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

10 SEP 2020 19:12

PC Open Date & Time

10 SEP 2020 16:01

PC Close Date & Time

11 SEP 2020 11:59

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 12:01

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 12:02

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 12:04

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 13:13

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 12:53

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 12:25

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

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 ☐

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 12:49
PC Open Date & Time	10 SEP 2020 12:36
PC Close Date & Time	10 SEP 2020 15:06

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

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 ☐

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 19:12
PC Open Date & Time	10 SEP 2020 16:01
PC Close Date & Time	11 SEP 2020 11:59

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

43 of 2127

EAB) (1725)

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:40

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

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:40

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 ☒

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:40

Yes ☐	
PC Time stamp	12 SEP 2020 12:03
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:40

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 ☒

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:40

Yes ☐	
PC Time stamp	13 SEP 2020 12:05
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

49 of 2127

EAB) (1725)

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:40

Yes ☐	
PC Time stamp	14 SEP 2020 13:13
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

51 of 2127

EAB) (1725)

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:40

Yes ☐	
PC Time stamp	15 SEP 2020 12:54
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 2127

EAB) (1725)

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:40

Yes ☐	
PC Time stamp	16 SEP 2020 12:27
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3572251

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:18:35

Generated On: 10 Jun 2021 08:20:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572251

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:18:35

Generated On: 10 Jun 2021 08:20:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572251

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:18:35

Generated On: 10 Jun 2021 08:20:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572251

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:18:35

Generated On: 10 Jun 2021 08:20:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572251

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:18:35

Generated On: 10 Jun 2021 08:20:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572251

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:18:35

Generated On: 10 Jun 2021 08:20:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572251

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Mar 2021 00:18:46

Generated On: 10 Jun 2021 08:20:40

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	06 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Mar 2021 00:18:46

Generated On: 10 Jun 2021 08:20:40

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	06 OCT 2020
Time of assessment (00:00-23:59)	12:30 (24 HR)
Vital Signs Date and Time (derived)	06 OCT 2020 12:30
Temperature (xxx.x)	97.7 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	73 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)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Mar 2021 00:18:46

Generated On: 10 Jun 2021 08:20:40

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	06 OCT 2020
Time of assessment (00:00-23:59)	13:53 (24 HR)
Vital Signs Date and Time (derived)	06 OCT 2020 13:53
Temperature (xxx.x)	97.3 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3572251

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Mar 2021 00:18:46

Generated On: 10 Jun 2021 08:20:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 OCT 2020

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

US3572251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Mar 2021 00:18:45

Generated On: 10 Jun 2021 08:20:40

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) 6 OCT 2020

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

Treatment Date and Time (derived) 6 OCT 2020 13:23

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

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

US3572251

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Mar 2021 00:18:46

Generated On: 10 Jun 2021 08:20:40

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

06 OCT 2020

Collection time (00:00-23:59)

12:37 (24 HR)

Collection date and time (derived)

06 OCT 2020 12:37

US3572251

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Mar 2021 00:18:35

Generated On: 10 Jun 2021 08:20:40

Collection date (dd MMM yyyy)			06 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:28	06 OCT 2020 12:28
Nasopharyngeal Swab 2	No		

US3572251

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:18:45

Generated On: 10 Jun 2021 08:20:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 13:54

PC Open Date & Time

06 OCT 2020 13:43

PC Close Date & Time

06 OCT 2020 16:13

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

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 97.1 °F

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

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

PC Time Stamp	06 OCT 2020 17:08
PC Open Date & Time	06 OCT 2020 17:08
PC Close Date & Time	07 OCT 2020 11:59

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:40

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

97.7 °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

07 OCT 2020 18:01

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:40

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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 12:09

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:40

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

09 OCT 2020 16:32

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:40

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

10 OCT 2020 22:56

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °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

11 OCT 2020 12:37

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:40

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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 OCT 2020 17:43

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

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

06 OCT 2020 13:54

PC Open Date & Time

06 OCT 2020 13:43

PC Close Date & Time

06 OCT 2020 16:13

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

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

06 OCT 2020 17:09

PC Open Date & Time

06 OCT 2020 17:08

PC Close Date & Time

07 OCT 2020 11:59

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 18:01

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 OCT 2020 12:09

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 OCT 2020 16:32

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 OCT 2020 22:57

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 OCT 2020 12:38

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 OCT 2020 17:44

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

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 ☐

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

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

No ☒

Yes ☐

PC Time stamp	06 OCT 2020 13:55
PC Open Date & Time	06 OCT 2020 13:43
PC Close Date & Time	06 OCT 2020 16:13

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

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 ☐

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

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

No ☒

Yes ☐

PC Time stamp	06 OCT 2020 17:09
PC Open Date & Time	06 OCT 2020 17:08
PC Close Date & Time	07 OCT 2020 11:59

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

89 of 2127

EAB) (1725)

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:40

Yes ☐	
PC Time stamp	07 OCT 2020 18:02
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

91 of 2127

EAB) (1725)

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:40

Yes ☐	
PC Time stamp	08 OCT 2020 12:10
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

93 of 2127

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:40

Yes ☐	
PC Time stamp	09 OCT 2020 16:33
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

95 of 2127

EAB) (1725)

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:40

Yes ☐	
PC Time stamp	10 OCT 2020 22:57
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

97 of 2127

EAB) (1725)

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:40

Yes ☐	
PC Time stamp	11 OCT 2020 12:38
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

99 of 2127

EAB) (1725)

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:40

Yes ☐	
PC Time stamp	12 OCT 2020 17:45
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3572251

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:18:35

Generated On: 10 Jun 2021 08:20:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572251

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:18:35

Generated On: 10 Jun 2021 08:20:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572251

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:18:35

Generated On: 10 Jun 2021 08:20:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572251

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:18:35

Generated On: 10 Jun 2021 08:20:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572251

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:18:35

Generated On: 10 Jun 2021 08:20:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572251

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:18:35

Generated On: 10 Jun 2021 08:20:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572251

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Mar 2021 00:18:46

Generated On: 10 Jun 2021 08:20:40

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3572251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Mar 2021 00:18:46

Generated On: 10 Jun 2021 08:20:40

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	11 DEC 2020
Time of assessment (00:00-23:59)	12:15 (24 HR)
Vital Signs Date and Time (derived)	11 DEC 2020 12:15
Temperature (xxx.x)	97.7 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	102 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3572251

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 04:57:12

Generated On: 10 Jun 2021 08:20:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 DEC 2020

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

US3572251

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Mar 2021 00:18:46

Generated On: 10 Jun 2021 08:20:40

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 DEC 2020

Collection time (00:00-23:59)

12:20 (24 HR)

Collection date and time (derived)

11 DEC 2020 12:20

US3572251

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:18:46

Generated On: 10 Jun 2021 08:20:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 NOV 2020 08:41:42
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3572251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 NOV 2020 06:38:34
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

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

Date and time of submission

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 00:07:09
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Date and time of submission	05 DEC 2020 00:07:25
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 01:54:53
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 DEC 2020 10:06:07

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

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

Date and time of submission

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

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

Date and time of submission

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

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

Date and time of submission

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

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

Date and time of submission

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

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

Date and time of submission

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 FEB 2021 14:51:55

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 07:49:48

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Date and time of submission	13 FEB 2021 00:01:58
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 FEB 2021 11:43:48

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 FEB 2021 12:25:35
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 MAR 2021 13:41:31
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 MAR 2021 04:22:33
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Date and time of submission	20 MAR 2021 00:04:42
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Date and time of submission	27 MAR 2021 20:57:00
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3572251

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:20:40

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 11:05:07

US3572251

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 04:21:24

Generated On: 10 Jun 2021 08:20:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572251

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 04:21:24

Generated On: 10 Jun 2021 08:20:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572251

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:57:11

Generated On: 10 Jun 2021 08:20:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572251

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:57:11

Generated On: 10 Jun 2021 08:20:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572251

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:57:12

Generated On: 10 Jun 2021 08:20:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572251

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:57:11

Generated On: 10 Jun 2021 08:20:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572251

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:57:12

Generated On: 10 Jun 2021 08:20:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572251

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:57:12

Generated On: 10 Jun 2021 08:20:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572251

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:40

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 _____

US3572251

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

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

US3572251

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:40

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.

US3572251

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:40

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

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

Collection date and time (derived)

US3572251

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:40

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 03 Apr 2021 04:57:02

Generated On: 10 Jun 2021 08:20:40

Date of Contact	11 DEC 2020
Time of Contact	12:00
Date and Time of Contact (derived)	11 DEC 2020 12:00
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 ☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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

Date	11 DEC 2020

Assessment Not Done	True

O2 Saturation	ND - Not Done

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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

	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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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

Date	12 DEC 2020

Assessment Not Done	False

O2 Saturation	ND - Not Done

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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

	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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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

Date	13 DEC 2020

Assessment Not Done	False

O2 Saturation	96 %

O2 Saturation Units	%

Temperature	98.0 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 ☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

	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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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 ☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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

Date	14 DEC 2020

Assessment Not Done	False

O2 Saturation	96 %

O2 Saturation Units	%

Temperature	97.7 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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

	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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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 ☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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

Date	15 DEC 2020

Assessment Not Done	False

O2 Saturation	98 %

O2 Saturation Units	%

Temperature	97.8 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 ☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

	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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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 ☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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

Date	16 DEC 2020

Assessment Not Done	False

O2 Saturation	97 %

O2 Saturation Units	%

Temperature	97.0 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 ☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

	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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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 ☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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

Date	17 DEC 2020

Assessment Not Done	False

O2 Saturation	95 %

O2 Saturation Units	%

Temperature	97.6 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 ☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

	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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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

Date	18 DEC 2020

Assessment Not Done	False

O2 Saturation	95 %

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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

	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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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

Date	19 DEC 2020

Assessment Not Done	False

O2 Saturation	97 %

O2 Saturation Units	%

Temperature	98.1 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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

	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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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 ☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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

Date	20 DEC 2020

Assessment Not Done	False

O2 Saturation	97 %

O2 Saturation Units	%

Temperature	97.6 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 ☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

	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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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 ☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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

Date	21 DEC 2020

Assessment Not Done	False

O2 Saturation	97 %

O2 Saturation Units	%

Temperature	97.6 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 ☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

	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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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

Date	22 DEC 2020

Assessment Not Done	False

O2 Saturation	96 %

O2 Saturation Units	%

Temperature	97.1 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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

	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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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 ☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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

Date	23 DEC 2020

Assessment Not Done	False

O2 Saturation	96 %

O2 Saturation Units	%

Temperature	97.1 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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

	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	☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 03 Apr 2021 04:57:03

Generated On: 10 Jun 2021 08:20:40

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 ☐

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 03 Apr 2021 04:57:02

Generated On: 10 Jun 2021 08:20:40

Date of Visit 11 DEC 2020

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

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

Date of Test 11 DEC 2020

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

Other, specify _____

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

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes ☐
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3572251

Folder: Covid-19 Assessment 24 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 03 Apr 2021 04:57:02

Generated On: 10 Jun 2021 08:20:40

Date of Contact	24 SEP 2020
Time of Contact	09:00
Date and Time of Contact (derived)	24 SEP 2020 09:00
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☒

US3572251

Folder: Covid-19 Assessment 24 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 03 Apr 2021 04:57:02

Generated On: 10 Jun 2021 08:20:40

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3572251

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 28 Apr 2021 10:11:59

Generated On: 10 Jun 2021 08:20:40

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	14 DEC 2020
Day 5	Yes	16 DEC 2020
Day 7	Yes	18 DEC 2020
Day 9	Yes	20 DEC 2020
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3572251

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 04:57:08

Generated On: 10 Jun 2021 08:20:40

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

US3572251

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 04:57:08

Generated On: 10 Jun 2021 08:20:40

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	11 DEC 2020
Time of assessment (00:00-23:59)	12:15 (24 HR)
Vital Signs Date and Time (derived)	11 DEC 2020 12:15
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	232.0 lb
Temperature (xxx.x)	97.7 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	102 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3572251

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 04:57:08

Generated On: 10 Jun 2021 08:20:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 DEC 2020

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

US3572251

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 03 Apr 2021 04:57:08

Generated On: 10 Jun 2021 08:20:40

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

11 DEC 2020

US3572251

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:40

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 _____

US3572251

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

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

US3572251

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:40

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.

US3572251

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 08:20:40

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection _____

US3572251

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

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 04:57:09

Generated On: 10 Jun 2021 08:20:40

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	02 FEB 2021

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

Folder OID	UNBLND_DECIDE

US3572251

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

Form: Unblinding

Data signed: (b) (4) 03 Apr 2021 04:57:09

Generated On: 10 Jun 2021 08:20:40

Date of updated informed consent (dd MMM yyyy) 02 FEB 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 02 FEB 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3572251

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 04:57:08

Generated On: 10 Jun 2021 08:20:40

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	02 FEB 2021
Collection time (00:00-23:59)	14:22 (24 HR)
Collection date and time (derived)	02 FEB 2021 14:22

US3572251

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 03 Apr 2021 04:57:08

Generated On: 10 Jun 2021 08:20:40

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	02 FEB 2021
Collection time (00:00 - 23:59)	16:30
Collection Date and Time (derived)	02 FEB 2021 16:30

US3572251

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 03 Apr 2021 04:56:59

Generated On: 10 Jun 2021 08:20:40

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 16:37:54

Generated On: 10 Jun 2021 08:20:40

AEID

Adverse event

ACUTE TRAUMATIC
AMPUTATION OF THE INDEX
FINGER AT THE LEVEL OF THE
MIDDLE PHALANX

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)

11 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

11 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

PRODUCTION RELEASE (v12.003

223 of 2127

EAB) (1725)

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 16:37:54

Generated On: 10 Jun 2021 08:20:40

	Unknown	☐
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:	SUBJECT WILL EXPERIENCE ONGOING LIMITATIONS AS A RESULT OF FINGER AMPUTATION	
Narrative		
Serious Adverse Event Derived (CSA Programming Field Only)	0	
Medically Attended AE Derived (CSA Programming Field Only)	1	

PRODUCTION RELEASE (v12.003

224 of 2127

EAB) (1725)

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 16:37:54

Generated On: 10 Jun 2021 08:20:40

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 16:37:54

Generated On: 10 Jun 2021 08:20:40

AEID	
Adverse event	HIGH CHOLESTEROL
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)	24 FEB 2021
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 ☐
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

226 of 2127

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 16:37:54

Generated On: 10 Jun 2021 08:20:40

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 SUBJECT WENT TO THE
DOCTOR FOR FOLLOW-UPS.
DURING THIS VISIT THE
SUBJECT GOT BLOOD WORK
DONE AND IT WAS DIAGNOSED
THAT SUBJECT HAS HIGH
CHOLESTEROL, MEDICATION IS
RECORDED IN THE CON. MED.
LOG

PRODUCTION RELEASE (v12.003
EAB) (1725)

227 of 2127

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 16:37:54

Generated On: 10 Jun 2021 08:20:40

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

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 16:37:54

Generated On: 10 Jun 2021 08:20:40

AEID

Adverse event

GASTRIC REFLUX

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)

2 FEB 2021

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 ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

229 of 2127

EAB) (1725)

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 16:37:54

Generated On: 10 Jun 2021 08:20:40

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 Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 16:37:54

Generated On: 10 Jun 2021 08:20:40

AEID	USA-US091-2021-MRNA-1273-P30 1000019
Adverse event	HEAD TRAUMA DUE TO FALL
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)	3 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	3 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	True
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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

231 of 2127

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 16:37:54

Generated On: 10 Jun 2021 08:20:40

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	True
Concomitant Medication	False
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	

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 16:37:54

Generated On: 10 Jun 2021 08:20:40

SUBJECT PASSED AWAY ON 03/APR/21. THE SAFETY CALL NURSE CONTACTED SUBJECT FOR E DIARY REMINDER ON 14APR2021 AND THE SUBJECT SISTER ANSWERED THE PHONE; THE SUBJECT HAD FAINTED AND HIT THEIR HEAD; THE SUBJECT WAS TAKEN TO A HOSPITAL (SISTER DOES NOT KNOW THE HOSPITAL NAME SINCE SUBJECT WAS IN ANOTHER COUNTY VISITING THEIR KIDS) WHERE THE SUBJECT DIED OF BLUNT HEAD TRAUMA. SISTER DOES NOT KNOW WHY DID THE SUBJECT FAINTED. SHE STATED THAT THE SUBJECT WAS NOT SICK. THE PI WAS NOTIFIED IMMEDIATELY AND THE CRA VIA EMAIL, IRB, EPIF AND EDC SUBMITTED 14APR2021. WILL ATTEMPT TO REQUEST ADDITIONAL INFORMATION IN ORDER TO REQUEST MEDICAL RECORDS. THE SUBJECT PRESENTS TO ER FOLLOWING FALL. THE ONSET WAS JUST PRIOR TO ARRIVAL. THE OCCURRENCE WAS SINGLE EPISODE. THE FALL WAS DESCRIBED AS FELL DOWN 10 STEPS. THE LOCATION WHERE THE INCIDENT OCCURED WAS

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 16:37:54

Generated On: 10 Jun 2021 08:20:40

AT HOME. LOCATION: RIGHT
SCALP. THE CHARACTER OF
SYMPTOMS IS SWELLING AND
BLEEDING. THE DEGREE IS
PRESENT IS SEVERE. CAUSE OF
DEATH: HEAD TRAUMA
ALCHOL
INTOXICATION, ACCIDENTAL
FALL DOWN STAIRS,
CARDIOPULMONARY ARREST

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

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 03 Apr 2021 04:57:01

Generated On: 10 Jun 2021 08:20:40

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

Yes ☒

No ☐

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

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 11 Apr 2021 07:12:04

Generated On: 10 Jun 2021 08:20:40

Name of Medication GLYXAMBI

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS TYPE 2

Dose per administration 25/5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

236 of 2127

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 11 Apr 2021 07:12:04

Generated On: 10 Jun 2021 08:20:40

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 JUL 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)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 11 Apr 2021 07:12:04

Generated On: 10 Jun 2021 08:20:40

Name of Medication NOVOLOG

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS TYPE 2

Dose per administration 14/7

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

14 IU BEFORE BREAKFAST, 7 IU
BEFORE DINNER

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

238 of 2127

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 11 Apr 2021 07:12:04

Generated On: 10 Jun 2021 08:20:40

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JUL 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	☐

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 11 Apr 2021 07:12:04

Generated On: 10 Jun 2021 08:20:40

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

240 of 2127

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 11 Apr 2021 07:12:04

Generated On: 10 Jun 2021 08:20:40

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JUL 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	☒

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 11 Apr 2021 07:12:04

Generated On: 10 Jun 2021 08:20:40

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication PAIN FOR FINGER
AMPUTATION

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

242 of 2127

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 11 Apr 2021 07:12:04

Generated On: 10 Jun 2021 08:20:40

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	10 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	30 NOV 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 11 Apr 2021 07:12:04

Generated On: 10 Jun 2021 08:20:40

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication PAIN IN AMPUTATED FINGER

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

244 of 2127

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 11 Apr 2021 07:12:04

Generated On: 10 Jun 2021 08:20:40

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	24 NOV 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 11 Apr 2021 07:12:04

Generated On: 10 Jun 2021 08:20:40

Name of Medication LANSOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication REFLUX

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

246 of 2127

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 11 Apr 2021 07:12:04

Generated On: 10 Jun 2021 08:20:40

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 FEB 2021	
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	☒

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 11 Apr 2021 07:12:04

Generated On: 10 Jun 2021 08:20:40

Name of Medication ATACAND

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 16/12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

248 of 2127

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 11 Apr 2021 07:12:04

Generated On: 10 Jun 2021 08:20:40

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 FEB 2021	
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	☒

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 11 Apr 2021 07:12:04

Generated On: 10 Jun 2021 08:20:40

Name of Medication LIPITOR

Prophylaxis Yes ☐
No ☒

Indication HIGH CHOLESTEROL

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

250 of 2127

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 11 Apr 2021 07:12:04

Generated On: 10 Jun 2021 08:20:40

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 FEB 2021
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	☒

US3572251

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 03 Apr 2021 04:57:02

Generated On: 10 Jun 2021 08:20:40

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3572251

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:20:40

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3572251

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 28 Apr 2021 10:11:59

Generated On: 10 Jun 2021 08:20:40

Date of study discontinuation/completion (dd MMM yyyy) 3 APR 2021

Reason for discontinuation

AE (specify)	☐
SAE (specify)	☐
Complete	☐
Death	☒
Lost To Follow-up	☐
Physician decision (specify)	☐
Pregnancy	☐
Protocol deviation (specify)	☐
Study Terminated By Sponsor	☐
Withdrawal of consent by participant (specify)	☐
Other	☐

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

If reason for discontinuation is Death, main cause of death

Adverse event	☒
Unknown	☐
Other	☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy) 3 APR 2021

Was autopsy performed?

Yes	☒
No	☐
Unknown	☐

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 03 Apr 2021 04:57:09

Generated On: 10 Jun 2021 08:20:40

SAEID	USA-US091-2021-MRNA-1273-P301000009
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	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 03 Apr 2021 04:57:09

Generated On: 10 Jun 2021 08:20:40

SAEID	USA-US091-2021-MRNA-1273-P301000009
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	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	03/FEB/2021 16:02
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

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 03 Apr 2021 04:57:09

Generated On: 10 Jun 2021 08:20:40

SAEID	USA-US091-2021-MRNA-1273-P301000009
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	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	08/FEB/2021 15:15
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

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Data signed: (b) (4) 03 Apr 2021 04:57:09

Generated On: 10 Jun 2021 08:20:40

SAEID	USA-US091-2021-MRNA-1273-P301000009
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	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	08/FEB/2021 15:29
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

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Data signed: (b) (4) 30 Apr 2021 16:37:54

Generated On: 10 Jun 2021 08:20:40

SAEID	USA-US091-2021-MRNA-1273-P301000019
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	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Apr 2021 16:37:54

Generated On: 10 Jun 2021 08:20:40

SAEID	USA-US091-2021-MRNA-1273-P301000019
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	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	15/APR/2021 10:29
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

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form (2)

Data signed: (b) (4) 30 Apr 2021 16:37:54

Generated On: 10 Jun 2021 08:20:40

SAEID	USA-US091-2021-MRNA-1273-P301000019
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	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	15/APR/2021 14:48
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

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form (3)

Data signed: (b) (4) 30 Apr 2021 16:37:54

Generated On: 10 Jun 2021 08:20:40

SAEID	USA-US091-2021-MRNA-1273-P301000019
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	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	19/APR/2021 08:59
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

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form (4)

Data signed: (b) (4) 30 Apr 2021 16:37:54

Generated On: 10 Jun 2021 08:20:40

SAEID	USA-US091-2021-MRNA-1273-P301000019
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	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	29/APR/2021 13:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3572251 (Prod: Laguna Clinical Research Associates)

US3572251

Form: Participant Creation

Generated On: 10 Jun 2021 08:20:40

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:42:09
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'US3572251'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 16:54:49

US3572251

Form: Participant Creation

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:20:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:15:34
User entered 'Yes (Y)'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 16:57:44

US3572251

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:15:34
User entered '10 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 16:54:50

US3572251

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:15:34
User entered 'Clinic (Clinic)'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 16:57:44

US3572251

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:20:40

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User entered 'SCRN'	System	10 Sep 2020 16:57:44

US3572251

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:40

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:22:15
User entered (b) (6) 1978'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 16:54:51

US3572251

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:40

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:22:15
User entered '41'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 16:59:55

US3572251

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:40

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User entered 'YEARS'	System	10 Sep 2020 16:59:55

US3572251

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:40

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User entered '42'	System	10 Sep 2020 17:00:19

US3572251

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:40

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:22:15
User entered 'Male (M)'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 16:59:55

US3572251

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:40

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:22:15
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 16:59:55

US3572251

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:40

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:22:15
User entered 'l'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 16:59:55

US3572251

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:40

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:22:15
User entered '0'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 16:59:55

US3572251

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:40

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:22:15
User entered '0'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 16:59:55

US3572251

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:40

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:22:15
User entered '0'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 16:59:55

US3572251

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:40

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:22:15
User entered '0'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 16:59:55

US3572251

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:40

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:22:15
User entered '0'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 16:59:55

US3572251

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:40

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:22:15
User entered empty.	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 16:59:55

US3572251

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:40

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:22:15
User entered '0'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 16:59:55

US3572251

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:20:40

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:22:15
User entered '0'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 16:59:55

US3572251

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:20:40

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:22:41
User entered '10 Sep 2020'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:00:19

US3572251

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User entered 'Sep 2020'	System	10 Sep 2020 17:00:19

US3572251

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User entered '2020'	System	10 Sep 2020 17:00:19

US3572251

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:20:40

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:22:41
User entered 'Amendment 3 (3)'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:00:19

US3572251

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:22:41
User entered 'Yes (Y)'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:00:19

US3572251

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:20:40

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:22:41
User entered empty.	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:00:19

US3572251

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:20:40

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:22:41
User entered empty.	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:00:19

US3572251

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:20:40

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:22:41
User entered 'No (N)'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:00:19

US3572251

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:20:40

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:22:41
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 16:54:50

US3572251

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:20:40

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User entered 'l'	System	10 Sep 2020 17:00:29

US3572251

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:24:12
User entered 'Yes (Y)'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:00:29

US3572251

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:20:40

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:45:42
User entered 'Yes (Y)'	Brett Potthoff (b) (4) (b) (4)	19 Sep 2020 04:14:46

US3572251

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:20:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:46:38
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4)	19 Sep 2020 04:17:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Sep 2020 04:17:38
Data point term sent to Coder	System	19 Sep 2020 04:16:34
User entered 'Diabetes Type 2'	Brett Potthoff (b) (4)	19 Sep 2020 04:15:57

US3572251

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:46:38
User entered 'UN Jul 2020'	Brett Potthoff (b) (4) (b) (4)	19 Sep 2020 04:15:57

US3572251

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:20:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:46:38
User entered '0'	Brett Potthoff (b) (4) (b) (4)	19 Sep 2020 04:15:57

US3572251

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:20:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:46:38
User entered 'Yes (Y)'	Brett Potthoff (b) (4) (b) (4)	19 Sep 2020 04:15:57

US3572251

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:46:38
User entered empty.	Brett Potthoff (b) (4) (b) (4)	19 Sep 2020 04:15:57

US3572251

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:20:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:46:38
User entered '0'	Brett Potthoff (b) (4) (b) (4)	19 Sep 2020 04:15:57

US3572251

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User entered 'Jul 2020'	System	19 Sep 2020 04:15:57

US3572251

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User entered '2020'	System	19 Sep 2020 04:15:57

US3572251

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User entered empty.	System	19 Sep 2020 04:15:57

US3572251

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User entered empty.	System	19 Sep 2020 04:15:57

US3572251

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:46:38
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4)	19 Sep 2020 04:18:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Sep 2020 04:18:38
Data point term sent to Coder	System	19 Sep 2020 04:17:35
User entered 'Hypertension'	Brett Potthoff (b) (4)	19 Sep 2020 04:17:08

US3572251

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:46:38
User entered 'UN Jul 2008'	Brett Potthoff (b) (4) (b) (4)	19 Sep 2020 04:17:08

US3572251

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:46:38
User entered '0'	Brett Potthoff (b) (4) (b) (4)	19 Sep 2020 04:17:08

US3572251

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:46:38
User entered 'Yes (Y)'	Brett Potthoff (b) (4) (b) (4)	19 Sep 2020 04:17:08

US3572251

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:46:38
User entered empty.	Brett Potthoff (b) (4) (b) (4)	19 Sep 2020 04:17:08

US3572251

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:46:38
User entered '0'	Brett Potthoff (b) (4) (b) (4)	19 Sep 2020 04:17:08

US3572251

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User entered 'Jul 2008'	System	19 Sep 2020 04:17:08

US3572251

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User entered '2008'	System	19 Sep 2020 04:17:08

US3572251

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User entered empty.	System	19 Sep 2020 04:17:08

US3572251

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User entered empty.	System	19 Sep 2020 04:17:08

US3572251

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:48:11
User closed query 'Please complete both screen and Day 1 vitals page.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 18:47:46
Query 'Please complete both screen and Day 1 vitals page.' answered with 'DATA ENTERED ' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 14:32:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 14:32:31
User opened query 'Please complete both screen and Day 1 vitals page.' (Site from CRA).	(b) (4), (b) (6)	28 Sep 2020 21:25:37
Query 'Please complete page.' canceled (Site from CRA).	(b) (4), (b) (6)	28 Sep 2020 21:25:18
User opened query 'Please complete page.' (Site from CRA).	(b) (4), (b) (6)	28 Sep 2020 21:24:52

US3572251

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:48:11
User entered '10 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 14:32:31

US3572251

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:48:11
User entered '12:00'	(b) (4), (b) (6)	01 Oct 2020 14:32:31

US3572251

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User entered '10 Sep 2020 12:00'	System	01 Oct 2020 14:32:31

US3572251

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:48:11
User entered '68' in	(b) (4), (b) (6)	01 Oct 2020 14:32:31
DataPoint set to visible.	System	10 Sep 2020 17:00:29

US3572251

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:48:11
User entered '222' lb	(b) (4), (b) (6)	01 Oct 2020 14:32:31
DataPoint set to visible.	System	10 Sep 2020 17:00:29

US3572251

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User entered '33.82556'	System	01 Oct 2020 14:32:31
DataPoint set to visible.	System	10 Sep 2020 17:00:29

US3572251

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User entered 'kg/m2'	System	01 Oct 2020 14:32:31
DataPoint set to visible.	System	10 Sep 2020 17:00:29

US3572251

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:48:11
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Oct 2020 14:32:31

US3572251

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:48:11
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 14:32:31

US3572251

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:48:11
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Oct 2020 14:32:31

US3572251

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:48:11
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Oct 2020 14:32:31

US3572251

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User entered 'bpm'	System	01 Oct 2020 14:32:31

US3572251

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:48:11
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Oct 2020 14:32:31

US3572251

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User entered 'breaths/min'	System	01 Oct 2020 14:32:31

US3572251

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:48:11
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Oct 2020 14:32:31

US3572251

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User entered 'mmHg'	System	01 Oct 2020 14:32:31

US3572251

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:48:11
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Oct 2020 14:32:31

US3572251

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User entered 'mmHg'	System	01 Oct 2020 14:32:31

US3572251

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36

US3572251

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36

US3572251

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:49:22
User entered 'Yes (Y)'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:00:45

US3572251

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:49:22
User entered '10 Sep 2020'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:00:45

US3572251

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:23:28
User entered 'Yes (Y)'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:02:04

US3572251

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:23:28
User entered 'No (N)'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:02:04

US3572251

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:23:28
User entered 'No (N)'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:02:04

US3572251

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:23:28
User entered 'No (N)'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:02:04

US3572251

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:23:28
User entered 'No (N)'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:02:04

US3572251

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:23:28
User entered 'No (N)'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:02:04

US3572251

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:23:28
User entered 'No (N)'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:02:04

US3572251

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:23:28
User entered 'No (N)'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:02:04

US3572251

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:40

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:23:28
User entered 'No (N)'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:02:04

US3572251

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:23:28
User entered 'No (N)'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:02:04

US3572251

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:40

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:23:28
User entered 'No (N)'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:02:04

US3572251

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:40

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:23:28
User entered 'No (N)'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:02:04

US3572251

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:40

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:23:28
User entered empty.	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:02:04

US3572251

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:40

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
User entered '0'	(b) (4) (u) (4), (b) (6)	10 Sep 2020 17:02:04

US3572251

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:40

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:23:28
User entered '0'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:02:04

US3572251

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:23:28
User entered '0'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:02:04

US3572251

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:23:28
User entered '0'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:02:04

US3572251

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:23:28
User entered '0'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:02:04

US3572251

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:23:28
User entered 'l'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:02:04

US3572251

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:40

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
User entered '0'	(b) (4) Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:02:04

US3572251

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:20:40

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:40:36
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:41:03
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 21:23:28
User entered empty.	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:02:04

US3572251

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:20:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:49:39
User entered 'Yes (Y)'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:00:59

US3572251

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:49:39
User entered '10 Sep 2020'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:00:59

US3572251

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:49:39
User entered 'Clinic (Clinic)'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:00:59

US3572251

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:20:40

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User entered 'VISIT1'	System	10 Sep 2020 17:00:59

US3572251

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:50:20
User entered '10 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 16:59:40

US3572251

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:20:40

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:50:20
User entered '146088'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 16:59:40

US3572251

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:50:20
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 16:59:40

US3572251

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:20:40

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)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:50:20
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 14:14:23

US3572251

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:20:40

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)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:50:20
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 14:14:23

US3572251

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:50:20
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 14:14:23

US3572251

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:20:40

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:50:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 14:14:23

US3572251

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:20:40

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:50:20
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 14:14:23

US3572251

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:20:40

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:50:20
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 14:14:23
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 06:00:39
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:00:38

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:20:40

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:52:45
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:20:40

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:52:45
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:20:40

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:52:45
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:20:40

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:52:45
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:52:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:52:45
User entered '10 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:52:45
User entered '12:00'	(b) (4), (b) (6)	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User entered '10 Sep 2020 12:00'	System	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:52:45
User entered '97.5' F	(b) (4), (b) (6)	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:52:45
User entered 'Other (Other)'	(b) (4), (b) (6)	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:52:45
User entered 'TEMPORAL'	(b) (4), (b) (6)	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4)	
	(u) (4), (b) (6)	15 Jan 2021 04:40:53
User closed query 'Per source, 52 is noted. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	15 Jan 2021 04:40:51
Query 'Per source, 52 is noted. Please review and reconcile. ' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 23:55:09
DataPoint Un-verified.	(b) (4), (b) (6)	16 Dec 2020 23:55:02
User entered '52' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 23:55:02
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:52:45
User opened query 'Per source, 52 is noted. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 18:51:25
User entered '57'	(b) (4), (b) (6)	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User entered 'bpm'	System	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:52:45
User entered '18'	(b) (4), (b) (6)	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User entered 'breaths/min'	System	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:52:45
User entered '153'	(b) (4), (b) (6)	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User entered 'mmHg'	System	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:52:45
User entered '102'	(b) (4), (b) (6)	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User entered 'mmHg'	System	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:20:40

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:52:45
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:20:40

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:52:45
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:52:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:52:45
User entered '10 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:52:45
User entered '12:46'	(b) (4), (b) (6)	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User entered '10 Sep 2020 12:46'	System	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:52:45
User entered '97.5' F	(b) (4), (b) (6)	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:52:45
User entered 'Other (Other)'	(b) (4), (b) (6)	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:52:45
User entered 'TEMPORAL'	(b) (4), (b) (6)	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4)	
	(u) (4), (b) (6)	15 Jan 2021 04:41:05
User closed query 'Per source, 57 is noted. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	15 Jan 2021 04:41:02
Query 'Per source, 57 is noted. Please review and reconcile.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 23:55:43
DataPoint Un-verified.	(b) (4), (b) (6)	16 Dec 2020 23:55:36
User entered '57' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 23:55:36
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:52:45
User opened query 'Per source, 57 is noted. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 18:52:39
User entered '52'	(b) (4), (b) (6)	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User entered 'bpm'	System	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:52:45
User entered '18'	(b) (4), (b) (6)	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User entered 'breaths/min'	System	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:52:45
User entered '141'	(b) (4), (b) (6)	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User entered 'mmHg'	System	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:52:45
User entered '88'	(b) (4), (b) (6)	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User entered 'mmHg'	System	01 Oct 2020 14:42:06

US3572251

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:52:51
User entered 'No (N)'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:01:21

US3572251

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:52:51
User entered empty.	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:01:21

US3572251

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:20:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:54:26
User entered 'Yes (Y)'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:23:37

US3572251

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:20:40

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:54:26
User entered empty.	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:23:37

US3572251

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:20:40

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)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:54:26
User entered empty.	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:23:37

US3572251

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:20:40

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 17:23:37

US3572251

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:20:40

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:54:26
User entered '10 Sep 2020'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:23:37

US3572251

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:20:40

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:54:26
User entered '12:16'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:23:37

US3572251

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:20:40

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User entered '10 Sep 2020 12:16'	System	10 Sep 2020 17:23:37

US3572251

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:20:40

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:54:26
User entered 'Left Arm (LEFT ARM)'	Brett Potthoff (b) (4) (b) (4)	10 Sep 2020 17:23:37

US3572251

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:20:40

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:54:26
User entered 'ONCE'	System	10 Sep 2020 17:23:37

US3572251

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:20:40

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 17:23:37

US3572251

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:52:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 14:34:55

US3572251

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:52:57
User entered '10 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 14:34:55

US3572251

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:40

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:52:57
User entered '12:05'	(b) (4), (b) (6)	01 Oct 2020 14:34:55

US3572251

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User entered '10 Sep 2020 12:05'	System	01 Oct 2020 14:34:55

US3572251

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:20:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:53:03
User entered '10 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 14:34:37

US3572251

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:20:40

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	01 Oct 2020 14:34:37

US3572251

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:20:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:53:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 14:34:37

US3572251

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:20:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:53:03
User entered '12:20'	(b) (4), (b) (6)	01 Oct 2020 14:34:37

US3572251

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:20:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User entered '10 Sep 2020 12:20'	System	01 Oct 2020 14:34:37

US3572251

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:20:40

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	01 Oct 2020 14:34:37

US3572251

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:20:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:53:03
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 14:34:37

US3572251

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:20:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:53:03
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 14:34:37

US3572251

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:20:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User entered empty.	System	01 Oct 2020 14:34:37

US3572251

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:20:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 18:54:51
User entered 'Yes (Y)'	Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 13:59:00

US3572251

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:20:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User entered 'I'	System	24 Sep 2020 13:59:00

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	10 Sep 2020 17:23:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T12:48:05', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'ccda0185-7bfb-4133-84a8-9aec9eb896d1' User entered 'Yes (Y)'	System	10 Sep 2020 17:48:27
	System	10 Sep 2020 17:48:27

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T12:48:11', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'ccda0185-7bfb-4133-84a8-9aec9eb896d1' User entered '97.5'	System	10 Sep 2020 17:48:27
	System	10 Sep 2020 17:48:27

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T12:48:17', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'ccda0185-7bfb-4133-84a8-9aec9eb896d1' User entered 'No (N)'	System	10 Sep 2020 17:48:27
	System	10 Sep 2020 17:48:27

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T12:48:24', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'ccda0185-7bfb-4133-84a8-9aec9eb896d1' User entered '10 Sep 2020 12:48'	System	10 Sep 2020 17:48:27
	System	10 Sep 2020 17:48:27

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '10 Sep 2020 12:36'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '10 Sep 2020 15:06'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	10 Sep 2020 17:23:37
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T19:10:53', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '468a8cf9-46b2-4f3c-9be9-255546d147be' User entered 'Yes (Y)'	System	11 Sep 2020 00:11:17
	System	11 Sep 2020 00:11:17

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T19:11:01', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '468a8cf9-46b2-4f3c-9be9-255546d147be' User entered '97.7'	System	11 Sep 2020 00:11:17
	System	11 Sep 2020 00:11:17

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T19:11:06', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '468a8cf9-46b2-4f3c-9be9-255546d147be' User entered 'No (N)'	System	11 Sep 2020 00:11:17
	System	11 Sep 2020 00:11:17

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T19:11:15', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '468a8cf9-46b2-4f3c-9be9-255546d147be' User entered '10 Sep 2020 19:11'	System	11 Sep 2020 00:11:17
	System	11 Sep 2020 00:11:17

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '10 Sep 2020 16:01'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	10 Sep 2020 17:23:37
User entered 'Day 2'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-11T12:00:19', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '8dbfce50-1da3-4c12-8d6a-21471b55a490' User entered 'Yes (Y)'	System	11 Sep 2020 17:01:16
	System	11 Sep 2020 17:01:16

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-11T12:00:34', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '8dbfce50-1da3-4c12-8d6a-21471b55a490' User entered '98.1'	System	11 Sep 2020 17:01:16
	System	11 Sep 2020 17:01:16

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-11T12:00:38', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '8dbfce50-1da3-4c12-8d6a-21471b55a490'	System	11 Sep 2020 17:01:16
User entered 'No (N)'	System	11 Sep 2020 17:01:16

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-11T12:00:46', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '8dbfce50-1da3-4c12-8d6a-21471b55a490'	System	11 Sep 2020 17:01:16
User entered '11 Sep 2020 12:00'	System	11 Sep 2020 17:01:16

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	10 Sep 2020 17:23:37
User entered 'Day 3'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-12T12:00:23', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '2ad7ff6f-9672-48bc-abb8-0581d78f2a4e' User entered 'Yes (Y)'	System	12 Sep 2020 17:00:58
	System	12 Sep 2020 17:00:58

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-12T12:00:34', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '2ad7ff6f-9672-48bc-abb8-0581d78f2a4e' User entered '97.9'	System	12 Sep 2020 17:00:58
	System	12 Sep 2020 17:00:58

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-12T12:00:38', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '2ad7ff6f-9672-48bc-abb8-0581d78f2a4e'	System	12 Sep 2020 17:00:58
User entered 'No (N)'	System	12 Sep 2020 17:00:58

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-12T12:00:41', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '2ad7ff6f-9672-48bc-abb8-0581d78f2a4e' User entered '12 Sep 2020 12:00'	System	12 Sep 2020 17:00:58
	System	12 Sep 2020 17:00:58

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	10 Sep 2020 17:23:37
User entered 'Day 4'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-13T12:04:08', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'b33228d3-968b-4d23-92b2-8d7f44582610' User entered 'Yes (Y)'	System	13 Sep 2020 17:04:24
	System	13 Sep 2020 17:04:24

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-13T12:04:13', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'b33228d3-968b-4d23-92b2-8d7f44582610' User entered '97.1'	System	13 Sep 2020 17:04:24
	System	13 Sep 2020 17:04:24

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-13T12:04:17', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'b33228d3-968b-4d23-92b2-8d7f44582610'	System	13 Sep 2020 17:04:24
User entered 'No (N)'	System	13 Sep 2020 17:04:24

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-13T12:04:23', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'b33228d3-968b-4d23-92b2-8d7f44582610' User entered '13 Sep 2020 12:04'	System	13 Sep 2020 17:04:24
	System	13 Sep 2020 17:04:24

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	10 Sep 2020 17:23:37
User entered 'Day 5'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-14T13:12:23', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '013ce66e-8dd6-42b7-a425-7c538d7cb709' User entered 'Yes (Y)'	System	14 Sep 2020 18:12:38
	System	14 Sep 2020 18:12:38

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-14T13:12:28', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '013ce66e-8dd6-42b7-a425-7c538d7cb709' User entered '97.1'	System	14 Sep 2020 18:12:38
	System	14 Sep 2020 18:12:38

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-14T13:12:31', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '013ce66e-8dd6-42b7-a425-7c538d7cb709'	System	14 Sep 2020 18:12:38
User entered 'No (N)'	System	14 Sep 2020 18:12:38

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-14T13:12:35', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '013ce66e-8dd6-42b7-a425-7c538d7cb709' User entered '14 Sep 2020 13:12'	System	14 Sep 2020 18:12:38
	System	14 Sep 2020 18:12:38

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	10 Sep 2020 17:23:37
User entered 'Day 6'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-15T12:53:03', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'af84dde9-4459-48e5-8c55-e2821a832502' User entered 'Yes (Y)'	System	15 Sep 2020 17:53:21
	System	15 Sep 2020 17:53:21

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-15T12:53:11', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'af84dde9-4459-48e5-8c55-e2821a832502' User entered '96.8'	System	15 Sep 2020 17:53:21
	System	15 Sep 2020 17:53:21

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-15T12:53:14', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'af84dde9-4459-48e5-8c55-e2821a832502'	System	15 Sep 2020 17:53:21
User entered 'No (N)'	System	15 Sep 2020 17:53:21

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-15T12:53:19', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'af84dde9-4459-48e5-8c55-e2821a832502'	System	15 Sep 2020 17:53:21
User entered '15 Sep 2020 12:53'	System	15 Sep 2020 17:53:21

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	10 Sep 2020 17:23:37
User entered 'Day 7'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-16T12:24:55', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '4272dffa-2e61-4f90-aace-b42190e97975' User entered 'Yes (Y)'	System	16 Sep 2020 17:25:10
	System	16 Sep 2020 17:25:10

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-16T12:25:00', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '4272dffa-2e61-4f90-aace-b42190e97975' User entered '97.6'	System	16 Sep 2020 17:25:10
	System	16 Sep 2020 17:25:10

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-16T12:25:04', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '4272dffa-2e61-4f90-aace-b42190e97975'	System	16 Sep 2020 17:25:10
User entered 'No (N)'	System	16 Sep 2020 17:25:10

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-16T12:25:07', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '4272dffa-2e61-4f90-aace-b42190e97975'	System	16 Sep 2020 17:25:10
User entered '16 Sep 2020 12:25'	System	16 Sep 2020 17:25:10

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	10 Sep 2020 17:23:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T12:48:35', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '8d41f15f-3ae7-41c7-bf09-4a5dec29618d' User entered 'None (1)'	System	10 Sep 2020 17:49:05
	System	10 Sep 2020 17:49:05

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T12:48:46', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '8d41f15f-3ae7-41c7-bf09-4a5dec29618d' User entered 'No (N)'	System	10 Sep 2020 17:49:05
	System	10 Sep 2020 17:49:05

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T12:48:52', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '8d41f15f-3ae7-41c7-bf09-4a5dec29618d' User entered 'No (N)'	System	10 Sep 2020 17:49:05
	System	10 Sep 2020 17:49:05

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T12:48:56', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '8d41f15f-3ae7-41c7-bf09-4a5dec29618d' User entered 'None (1)'	System	10 Sep 2020 17:49:05
	System	10 Sep 2020 17:49:05

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T12:49:00', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '8d41f15f-3ae7-41c7-bf09-4a5dec29618d' User entered '10 Sep 2020 12:49'	System	10 Sep 2020 17:49:05
	System	10 Sep 2020 17:49:05

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '10 Sep 2020 12:36'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '10 Sep 2020 15:06'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	10 Sep 2020 17:23:37
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T19:11:45', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'bee3e0e3-b364-4a7d-8c93-9102f9418731' User entered 'None (1)'	System	11 Sep 2020 00:12:21
	System	11 Sep 2020 00:12:21

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T19:11:56', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'bee3e0e3-b364-4a7d-8c93-9102f9418731'	System	11 Sep 2020 00:12:21
User entered 'No (N)'	System	11 Sep 2020 00:12:21

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T19:12:04', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'bee3e0e3-b364-4a7d-8c93-9102f9418731'	System	11 Sep 2020 00:12:21
User entered 'No (N)'	System	11 Sep 2020 00:12:21

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T19:12:11', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'bee3e0e3-b364-4a7d-8c93-9102f9418731' User entered 'None (1)'	System	11 Sep 2020 00:12:21
	System	11 Sep 2020 00:12:21

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T19:12:18', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'bee3e0e3-b364-4a7d-8c93-9102f9418731' User entered '10 Sep 2020 19:12'	System	11 Sep 2020 00:12:21
	System	11 Sep 2020 00:12:21

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '10 Sep 2020 16:01'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	10 Sep 2020 17:23:37
User entered 'Day 2'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-11T12:01:15', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '64efd7c3-a58f-4629-9ec0-8957371f4621'	System	11 Sep 2020 17:02:33
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 17:02:33

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-11T12:01:20', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '64efd7c3-a58f-4629-9ec0-8957371f4621' User entered 'No (N)'	System	11 Sep 2020 17:02:33
	System	11 Sep 2020 17:02:33

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-11T12:01:30', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '64efd7c3-a58f-4629-9ec0-8957371f4621' User entered 'No (N)'	System	11 Sep 2020 17:02:33
	System	11 Sep 2020 17:02:33

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-11T12:01:35', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '64efd7c3-a58f-4629-9ec0-8957371f4621'	System	11 Sep 2020 17:02:33
User entered 'None (1)'	System	11 Sep 2020 17:02:33

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-11T12:01:41', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '64efd7c3-a58f-4629-9ec0-8957371f4621' User entered '11 Sep 2020 12:01'	System	11 Sep 2020 17:02:33
	System	11 Sep 2020 17:02:33

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	10 Sep 2020 17:23:37
User entered 'Day 3'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-12T12:00:53', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '4b3c786f-1178-47a5-95b0-5e94aa087a1b'	System	12 Sep 2020 17:02:53
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 17:02:53

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-12T12:00:58', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '4b3c786f-1178-47a5-95b0-5e94aa087a1b' User entered 'No (N)'	System	12 Sep 2020 17:02:53
	System	12 Sep 2020 17:02:53

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-12T12:01:54', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '4b3c786f-1178-47a5-95b0-5e94aa087a1b' User entered 'No (N)'	System	12 Sep 2020 17:02:53
	System	12 Sep 2020 17:02:53

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-12T12:01:58', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '4b3c786f-1178-47a5-95b0-5e94aa087a1b' User entered 'None (1)'	System	12 Sep 2020 17:02:53
	System	12 Sep 2020 17:02:53

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-12T12:02:04', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '4b3c786f-1178-47a5-95b0-5e94aa087a1b' User entered '12 Sep 2020 12:02'	System	12 Sep 2020 17:02:53
	System	12 Sep 2020 17:02:53

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	10 Sep 2020 17:23:37
User entered 'Day 4'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-13T12:04:30', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '990a0868-b928-4c30-95d4-e93d2b0e1211'	System	13 Sep 2020 17:04:53
User entered 'None (1)'	System	13 Sep 2020 17:04:53

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-13T12:04:33', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '990a0868-b928-4c30-95d4-e93d2b0e1211'	System	13 Sep 2020 17:04:53
User entered 'No (N)'	System	13 Sep 2020 17:04:53

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-13T12:04:37', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '990a0868-b928-4c30-95d4-e93d2b0e1211'	System	13 Sep 2020 17:04:53
User entered 'No (N)'	System	13 Sep 2020 17:04:53

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-13T12:04:40', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '990a0868-b928-4c30-95d4-e93d2b0e1211'	System	13 Sep 2020 17:04:53
User entered 'None (1)'	System	13 Sep 2020 17:04:53

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-13T12:04:51', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '990a0868-b928-4c30-95d4-e93d2b0e1211'	System	13 Sep 2020 17:04:53
User entered '13 Sep 2020 12:04'	System	13 Sep 2020 17:04:53

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	10 Sep 2020 17:23:37
User entered 'Day 5'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-14T13:12:38', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'a96bc0de-67b3-4104-acf2-3f09acc50af0'	System	14 Sep 2020 18:13:03
User entered 'None (1)'	System	14 Sep 2020 18:13:03

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-14T13:12:41', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'a96bc0de-67b3-4104-acf2-3f09acc50af0' User entered 'No (N)'	System	14 Sep 2020 18:13:03
	System	14 Sep 2020 18:13:03

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-14T13:12:44', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'a96bc0de-67b3-4104-acf2-3f09acc50af0' User entered 'No (N)'	System	14 Sep 2020 18:13:03
	System	14 Sep 2020 18:13:03

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-14T13:12:49', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'a96bc0de-67b3-4104-acf2-3f09acc50af0'	System	14 Sep 2020 18:13:03
User entered 'None (1)'	System	14 Sep 2020 18:13:03

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-14T13:13:00', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'a96bc0de-67b3-4104-acf2-3f09acc50af0' User entered '14 Sep 2020 13:13'	System	14 Sep 2020 18:13:03
	System	14 Sep 2020 18:13:03

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	10 Sep 2020 17:23:37
User entered 'Day 6'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-15T12:53:39', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '76212164-64ed-4b90-b438-75cef45b8c7c' User entered 'None (1)'	System	15 Sep 2020 17:53:50
	System	15 Sep 2020 17:53:50

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-15T12:53:26', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '76212164-64ed-4b90-b438-75cef45b8c7c' User entered 'No (N)'	System	15 Sep 2020 17:53:50
	System	15 Sep 2020 17:53:50

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-15T12:53:31', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '76212164-64ed-4b90-b438-75cef45b8c7c' User entered 'No (N)'	System	15 Sep 2020 17:53:50
	System	15 Sep 2020 17:53:50

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-15T12:53:34', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '76212164-64ed-4b90-b438-75cef45b8c7c' User entered 'None (1)'	System	15 Sep 2020 17:53:50
	System	15 Sep 2020 17:53:50

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-15T12:53:44', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '76212164-64ed-4b90-b438-75cef45b8c7c' User entered '15 Sep 2020 12:53'	System	15 Sep 2020 17:53:50
	System	15 Sep 2020 17:53:50

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	10 Sep 2020 17:23:37
User entered 'Day 7'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-16T12:25:20', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '4d7e63e8-267e-489c-9c1a-71334a098c54' User entered 'None (1)'	System	16 Sep 2020 17:25:43
	System	16 Sep 2020 17:25:43

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-16T12:25:23', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '4d7e63e8-267e-489c-9c1a-71334a098c54' User entered 'No (N)'	System	16 Sep 2020 17:25:43
	System	16 Sep 2020 17:25:43

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-16T12:25:27', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '4d7e63e8-267e-489c-9c1a-71334a098c54' User entered 'No (N)'	System	16 Sep 2020 17:25:43
	System	16 Sep 2020 17:25:43

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-16T12:25:32', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '4d7e63e8-267e-489c-9c1a-71334a098c54' User entered 'None (1)'	System	16 Sep 2020 17:25:43
	System	16 Sep 2020 17:25:43

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-16T12:25:39', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '4d7e63e8-267e-489c-9c1a-71334a098c54' User entered '16 Sep 2020 12:25'	System	16 Sep 2020 17:25:43
	System	16 Sep 2020 17:25:43

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	10 Sep 2020 17:23:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T12:49:07', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '9144eaa9-4e9a-428c-a597-92364fd77cc8' User entered 'None (0)'	System	10 Sep 2020 17:49:37
	System	10 Sep 2020 17:49:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T12:49:12', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '9144eaa9-4e9a-428c-a597-92364fd77cc8' User entered 'None (0)'	System	10 Sep 2020 17:49:37
	System	10 Sep 2020 17:49:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T12:49:17', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '9144eaa9-4e9a-428c-a597-92364fd77cc8' User entered 'None (0)'	System	10 Sep 2020 17:49:37
	System	10 Sep 2020 17:49:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T12:49:20', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '9144eaa9-4e9a-428c-a597-92364fd77cc8' User entered 'None (0)'	System	10 Sep 2020 17:49:37
	System	10 Sep 2020 17:49:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T12:49:23', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '9144eaa9-4e9a-428c-a597-92364fd77cc8' User entered 'None (0)'	System	10 Sep 2020 17:49:37
	System	10 Sep 2020 17:49:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T12:49:26', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '9144eaa9-4e9a-428c-a597-92364fd77cc8' User entered 'None (0)'	System	10 Sep 2020 17:49:37
	System	10 Sep 2020 17:49:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

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)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T12:49:31', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '9144eaa9-4e9a-428c-a597-92364fd77cc8' User entered 'No (N)'	System	10 Sep 2020 17:49:37
	System	10 Sep 2020 17:49:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T12:49:34', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '9144eaa9-4e9a-428c-a597-92364fd77cc8' User entered '10 Sep 2020 12:49'	System	10 Sep 2020 17:49:37
	System	10 Sep 2020 17:49:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '10 Sep 2020 12:36'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '10 Sep 2020 15:06'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	10 Sep 2020 17:23:37
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T19:12:23', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'd77de008-2c6f-4900-a986-9f6b3ce336c5' User entered 'None (0)'	System	11 Sep 2020 00:12:58
	System	11 Sep 2020 00:12:58

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T19:12:26', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'd77de008-2c6f-4900-a986-9f6b3ce336c5' User entered 'None (0)'	System	11 Sep 2020 00:12:58
	System	11 Sep 2020 00:12:58

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T19:12:30', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'd77de008-2c6f-4900-a986-9f6b3ce336c5' User entered 'None (0)'	System	11 Sep 2020 00:12:58
	System	11 Sep 2020 00:12:58

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T19:12:34', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'd77de008-2c6f-4900-a986-9f6b3ce336c5' User entered 'None (0)'	System	11 Sep 2020 00:12:58
	System	11 Sep 2020 00:12:58

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T19:12:37', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'd77de008-2c6f-4900-a986-9f6b3ce336c5' User entered 'None (0)'	System	11 Sep 2020 00:12:58
	System	11 Sep 2020 00:12:58

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T19:12:40', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'd77de008-2c6f-4900-a986-9f6b3ce336c5' User entered 'None (0)'	System	11 Sep 2020 00:12:58
	System	11 Sep 2020 00:12:58

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

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)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T19:12:47', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'd77de008-2c6f-4900-a986-9f6b3ce336c5' User entered 'No (N)'	System	11 Sep 2020 00:12:58
	System	11 Sep 2020 00:12:58

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-10T19:12:54', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'd77de008-2c6f-4900-a986-9f6b3ce336c5' User entered '10 Sep 2020 19:12'	System	11 Sep 2020 00:12:58
	System	11 Sep 2020 00:12:58

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '10 Sep 2020 16:01'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	10 Sep 2020 17:23:37
User entered 'Day 2'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-11T12:01:45', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'd4e83610-0e28-4d66-977a-81cdaa848ffe' User entered 'None (0)'	System	11 Sep 2020 17:04:00
	System	11 Sep 2020 17:04:00

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-11T12:01:47', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'd4e83610-0e28-4d66-977a-81cdaa848ffe' User entered 'None (0)'	System	11 Sep 2020 17:04:00
	System	11 Sep 2020 17:04:00

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-11T12:01:51', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'd4e83610-0e28-4d66-977a-81cdaa848ffe' User entered 'None (0)'	System	11 Sep 2020 17:04:00
	System	11 Sep 2020 17:04:00

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-11T12:02:01', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'd4e83610-0e28-4d66-977a-81cdaa848ffe' User entered 'None (0)'	System	11 Sep 2020 17:04:00
	System	11 Sep 2020 17:04:00

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-11T12:02:04', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'd4e83610-0e28-4d66-977a-81cdaa848ffe' User entered 'None (0)'	System	11 Sep 2020 17:04:00
	System	11 Sep 2020 17:04:00

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-11T12:02:08', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'd4e83610-0e28-4d66-977a-81cdaa848ffe' User entered 'None (0)'	System	11 Sep 2020 17:04:00
	System	11 Sep 2020 17:04:00

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:40

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)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-11T12:02:28', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'd4e83610-0e28-4d66-977a-81cdaa848ffe' User entered 'No (N)'	System	11 Sep 2020 17:04:00
	System	11 Sep 2020 17:04:00

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-11T12:02:39', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'd4e83610-0e28-4d66-977a-81cdaa848ffe' User entered '11 Sep 2020 12:02'	System	11 Sep 2020 17:04:00
	System	11 Sep 2020 17:04:00

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	10 Sep 2020 17:23:37
User entered 'Day 3'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-12T12:02:08', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'c9aa0f7b-b75d-4213-8f94-f7d10849d208' User entered 'None (0)'	System	12 Sep 2020 17:03:50
	System	12 Sep 2020 17:03:50

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-12T12:02:11', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'c9aa0f7b-b75d-4213-8f94-f7d10849d208' User entered 'None (0)'	System	12 Sep 2020 17:03:50
	System	12 Sep 2020 17:03:50

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-12T12:02:15', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'c9aa0f7b-b75d-4213-8f94-f7d10849d208' User entered 'None (0)'	System	12 Sep 2020 17:03:50
	System	12 Sep 2020 17:03:50

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-12T12:02:20', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'c9aa0f7b-b75d-4213-8f94-f7d10849d208' User entered 'None (0)'	System	12 Sep 2020 17:03:50
	System	12 Sep 2020 17:03:50

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-12T12:02:22', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'c9aa0f7b-b75d-4213-8f94-f7d10849d208' User entered 'None (0)'	System	12 Sep 2020 17:03:50
	System	12 Sep 2020 17:03:50

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-12T12:02:27', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'c9aa0f7b-b75d-4213-8f94-f7d10849d208' User entered 'None (0)'	System	12 Sep 2020 17:03:50
	System	12 Sep 2020 17:03:50

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:40

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)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-12T12:02:35', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'c9aa0f7b-b75d-4213-8f94-f7d10849d208' User entered 'No (N)'	System	12 Sep 2020 17:03:50
	System	12 Sep 2020 17:03:50

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-12T12:03:36', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'c9aa0f7b-b75d-4213-8f94-f7d10849d208' User entered '12 Sep 2020 12:03'	System	12 Sep 2020 17:03:50
	System	12 Sep 2020 17:03:50

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	10 Sep 2020 17:23:37
User entered 'Day 4'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-13T12:04:54', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '556c8c24-c893-4f1d-8b95-c178848c9544' User entered 'None (0)'	System	13 Sep 2020 17:05:16
	System	13 Sep 2020 17:05:16

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-13T12:04:56', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '556c8c24-c893-4f1d-8b95-c178848c9544' User entered 'None (0)'	System	13 Sep 2020 17:05:16
	System	13 Sep 2020 17:05:16

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-13T12:04:59', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '556c8c24-c893-4f1d-8b95-c178848c9544' User entered 'None (0)'	System	13 Sep 2020 17:05:16
	System	13 Sep 2020 17:05:16

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-13T12:05:02', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '556c8c24-c893-4f1d-8b95-c178848c9544' User entered 'None (0)'	System	13 Sep 2020 17:05:16
	System	13 Sep 2020 17:05:16

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-13T12:05:04', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '556c8c24-c893-4f1d-8b95-c178848c9544' User entered 'None (0)'	System	13 Sep 2020 17:05:16
	System	13 Sep 2020 17:05:16

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-13T12:05:06', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '556c8c24-c893-4f1d-8b95-c178848c9544' User entered 'None (0)'	System	13 Sep 2020 17:05:16
	System	13 Sep 2020 17:05:16

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:40

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)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-13T12:05:09', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '556c8c24-c893-4f1d-8b95-c178848c9544' User entered 'No (N)'	System	13 Sep 2020 17:05:16
	System	13 Sep 2020 17:05:16

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-13T12:05:13', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '556c8c24-c893-4f1d-8b95-c178848c9544' User entered '13 Sep 2020 12:05'	System	13 Sep 2020 17:05:16
	System	13 Sep 2020 17:05:16

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	10 Sep 2020 17:23:37
User entered 'Day 5'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-14T13:13:05', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'e288de4b-1e25-4a8b-8be8-27eea7c57c64' User entered 'None (0)'	System	14 Sep 2020 18:13:25
	System	14 Sep 2020 18:13:25

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-14T13:13:07', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'e288de4b-1e25-4a8b-8be8-27eea7c57c64' User entered 'None (0)'	System	14 Sep 2020 18:13:25
	System	14 Sep 2020 18:13:25

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-14T13:13:09', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'e288de4b-1e25-4a8b-8be8-27eea7c57c64' User entered 'None (0)'	System	14 Sep 2020 18:13:25
	System	14 Sep 2020 18:13:25

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-14T13:13:12', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'e288de4b-1e25-4a8b-8be8-27eea7c57c64' User entered 'None (0)'	System	14 Sep 2020 18:13:25
	System	14 Sep 2020 18:13:25

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-14T13:13:14', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'e288de4b-1e25-4a8b-8be8-27eea7c57c64' User entered 'None (0)'	System	14 Sep 2020 18:13:25
	System	14 Sep 2020 18:13:25

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-14T13:13:17', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'e288de4b-1e25-4a8b-8be8-27eea7c57c64' User entered 'None (0)'	System	14 Sep 2020 18:13:25
	System	14 Sep 2020 18:13:25

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:40

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)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-14T13:13:21', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'e288de4b-1e25-4a8b-8be8-27eea7c57c64' User entered 'No (N)'	System	14 Sep 2020 18:13:25
	System	14 Sep 2020 18:13:25

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-14T13:13:23', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'e288de4b-1e25-4a8b-8be8-27eea7c57c64'	System	14 Sep 2020 18:13:25
User entered '14 Sep 2020 13:13'	System	14 Sep 2020 18:13:25

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	10 Sep 2020 17:23:37
User entered 'Day 6'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-15T12:53:47', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '53f9b8a5-9aa5-4111-8afc-8a099c6bb33c' User entered 'None (0)'	System	15 Sep 2020 17:54:05
	System	15 Sep 2020 17:54:05

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-15T12:53:49', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '53f9b8a5-9aa5-4111-8afc-8a099c6bb33c' User entered 'None (0)'	System	15 Sep 2020 17:54:05
	System	15 Sep 2020 17:54:05

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-15T12:53:50', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '53f9b8a5-9aa5-4111-8afc-8a099c6bb33c' User entered 'None (0)'	System	15 Sep 2020 17:54:05
	System	15 Sep 2020 17:54:05

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-15T12:53:52', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '53f9b8a5-9aa5-4111-8afc-8a099c6bb33c' User entered 'None (0)'	System	15 Sep 2020 17:54:05
	System	15 Sep 2020 17:54:05

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-15T12:53:53', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '53f9b8a5-9aa5-4111-8afc-8a099c6bb33c' User entered 'None (0)'	System	15 Sep 2020 17:54:05
	System	15 Sep 2020 17:54:05

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-15T12:53:55', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '53f9b8a5-9aa5-4111-8afc-8a099c6bb33c' User entered 'None (0)'	System	15 Sep 2020 17:54:05
	System	15 Sep 2020 17:54:05

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:40

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)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-15T12:53:58', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '53f9b8a5-9aa5-4111-8afc-8a099c6bb33c' User entered 'No (N)'	System	15 Sep 2020 17:54:05
	System	15 Sep 2020 17:54:05

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-15T12:54:02', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '53f9b8a5-9aa5-4111-8afc-8a099c6bb33c'	System	15 Sep 2020 17:54:05
User entered '15 Sep 2020 12:54'	System	15 Sep 2020 17:54:05

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	10 Sep 2020 17:23:37
User entered 'Day 7'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-16T12:25:48', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '23ea397d-39b4-469f-bdfa-fc5f21ce1b78' User entered 'None (0)'	System	16 Sep 2020 17:27:06
	System	16 Sep 2020 17:27:06

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-16T12:25:51', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '23ea397d-39b4-469f-bdfa-fc5f21ce1b78'	System	16 Sep 2020 17:27:06
User entered 'None (0)'	System	16 Sep 2020 17:27:06

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-16T12:25:55', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '23ea397d-39b4-469f-bdfa-fc5f21ce1b78'	System	16 Sep 2020 17:27:06
User entered 'None (0)'	System	16 Sep 2020 17:27:06

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-16T12:25:57', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '23ea397d-39b4-469f-bdfa-fc5f21ce1b78' User entered 'None (0)'	System	16 Sep 2020 17:27:06
	System	16 Sep 2020 17:27:06

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-16T12:25:59', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '23ea397d-39b4-469f-bdfa-fc5f21ce1b78' User entered 'None (0)'	System	16 Sep 2020 17:27:06
	System	16 Sep 2020 17:27:06

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-16T12:26:02', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '23ea397d-39b4-469f-bdfa-fc5f21ce1b78' User entered 'None (0)'	System	16 Sep 2020 17:27:06
	System	16 Sep 2020 17:27:06

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:40

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)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-16T12:26:12', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '23ea397d-39b4-469f-bdfa-fc5f21ce1b78'	System	16 Sep 2020 17:27:06
User entered 'No (N)'	System	16 Sep 2020 17:27:06

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-09-16T12:27:02', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '23ea397d-39b4-469f-bdfa-fc5f21ce1b78'	System	16 Sep 2020 17:27:06
User entered '16 Sep 2020 12:27'	System	16 Sep 2020 17:27:06

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 17:23:37

US3572251

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 17:23:37

US3572251

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	30 Oct 2020 18:17:44
User entered 'Yes (Y)'	Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 13:59:12

US3572251

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	30 Oct 2020 18:17:44
User entered '17 Sep 2020'	Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 13:59:12

US3572251

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	30 Oct 2020 18:17:44
User entered 'Contact Made (CONTACT MADE)'	Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 13:59:12

US3572251

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:09:08
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	30 Oct 2020 18:17:44
User entered empty.	Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 13:59:12

US3572251

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:08:48
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	30 Oct 2020 18:17:47
User entered 'Yes (Y)'	Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 13:59:19

US3572251

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:08:48
User entered 'l'	System	24 Sep 2020 13:59:19

US3572251

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:08:48
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	30 Oct 2020 18:17:56
User entered 'Yes (Y)'	Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:15:46

US3572251

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:08:48
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	30 Oct 2020 18:17:56
User entered '24 Sep 2020'	Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:15:46

US3572251

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:08:48
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	30 Oct 2020 18:17:56
User entered 'Contact Made (CONTACT MADE)'	Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:15:46

US3572251

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:08:48
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	30 Oct 2020 18:17:56
User entered empty.	Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:15:46

US3572251

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:08:48
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	30 Oct 2020 18:18:00
User entered 'Yes (Y)'	Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:15:52

US3572251

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:08:48
User entered 'l'	System	24 Sep 2020 14:15:52

US3572251

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:34:21
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 6OCT2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	02 Feb 2021 12:34:15
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 6OCT2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'EDC immunogenicity assessment is updated accordingly for Visit 2 Day 29' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 19:19:45
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 18:18:10
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 6OCT2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 06:36:29
User entered 'Yes (Y)'	Jessica McDowell (b) (4) (b) (4)	01 Oct 2020 22:01:33

US3572251

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:34:21
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 6OCT2020 is reported under Visit 2 Day 29visit in PPD Central lab, however swab sample is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	02 Feb 2021 11:00:30
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 6OCT2020 is reported under Visit 2 Day 29visit in PPD Central lab, however swab sample is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'EDC is updated accordingly for swab sample for Visit 2 Day 29' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 19:20:35
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 6OCT2020 is reported under Visit 2 Day 29visit in PPD Central lab, however swab sample is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 06:15:41
Query 'Per GCL Reconciliation: Swab sample collected on 06OCT2020 is labelled under "Unscheduled Visit COVID" in Viracor data and in GCL it is labelled under "Visit 2 Day 29". Please verify the correct visit for sample collected on this date. ' canceled (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 06:15:22
User opened query 'Per GCL Reconciliation: Swab sample collected on 06OCT2020 is labelled under "Unscheduled Visit COVID" in Viracor data and in GCL it is labelled under "Visit 2 Day 29". Please verify the correct visit for sample collected on this date. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 05:27:40
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 18:18:10
User entered '1 Oct 2020'	Jessica McDowell (b) (4) (b) (4)	01 Oct 2020 22:01:33

US3572251

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:34:21
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	30 Oct 2020 18:18:10
User entered 'Contact Made (CONTACT MADE)'	Jessica McDowell (b) (4) (b) (4)	01 Oct 2020 22:01:33

US3572251

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:34:21
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	30 Oct 2020 18:18:10
User entered empty.	Jessica Mcdowell (b) (4) (b) (4)	01 Oct 2020 22:01:33

US3572251

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:34:21
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
User closed query 'Please complete Day 29 data entry.' (Site from CRA).	(b) (4)	
Query 'Please complete Day 29 data entry.' answered with 'Day 29 entered' (Site from CRA).	(u) (4), (b) (6)	28 Feb 2021 18:11:14
User opened query 'Please complete Day 29 data entry.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 09:05:51
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:25:53
	(b) (4), (b) (6)	30 Oct 2020 18:18:13
User entered 'Yes (Y)'	Jessica McDowell (b) (4)	01 Oct 2020 22:01:39
	(b) (4)	

US3572251

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:34:21
User entered 'l'	System	01 Oct 2020 22:01:39

US3572251

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:48:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 23:35:10

US3572251

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:48:02
User entered '06 Oct 2020'	(b) (4), (b) (6)	15 Dec 2020 23:35:10

US3572251

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:48:02
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	15 Dec 2020 23:35:10

US3572251

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:40

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User entered 'VISIT2'	System	15 Dec 2020 23:35:10

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:51:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:51:26
User entered '06 Oct 2020'	(b) (4), (b) (6)	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:51:26
User entered '12:30'	(b) (4), (b) (6)	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User entered '06 Oct 2020 12:30'	System	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:51:26
User entered '97.7' F	(b) (4), (b) (6)	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:51:26
User entered 'Other (Other)'	(b) (4), (b) (6)	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:51:26
User entered 'temporal'	(b) (4), (b) (6)	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:51:26
User entered '73'	(b) (4), (b) (6)	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User entered 'bpm'	System	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:51:26
User entered '18'	(b) (4), (b) (6)	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User entered 'breaths/min'	System	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:51:26
User entered '135'	(b) (4), (b) (6)	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User entered 'mmHg'	System	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:51:26
User entered '82'	(b) (4), (b) (6)	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:20:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User entered 'mmHg'	System	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:51:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:51:26
User entered '06 Oct 2020'	(b) (4), (b) (6)	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:51:26
User entered '13:53'	(b) (4), (b) (6)	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User entered '06 Oct 2020 13:53'	System	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:51:26
User entered '97.3' F	(b) (4), (b) (6)	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:51:26
User entered 'Other (Other)'	(b) (4), (b) (6)	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:51:26
User entered 'temporal'	(b) (4), (b) (6)	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:51:26
User entered '59'	(b) (4), (b) (6)	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User entered 'bpm'	System	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:51:26
User entered '18'	(b) (4), (b) (6)	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User entered 'breaths/min'	System	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:51:26
User entered '134'	(b) (4), (b) (6)	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User entered 'mmHg'	System	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:51:26
User entered '90'	(b) (4), (b) (6)	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:20:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User entered 'mmHg'	System	15 Dec 2020 23:36:40

US3572251

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:51:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 23:36:55

US3572251

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:40

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:51:40
User entered '06 Oct 2020'	(b) (4), (b) (6)	15 Dec 2020 23:36:55

US3572251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:20:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:51:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 18:21:19

US3572251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:20:40

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:51:55
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 18:21:19

US3572251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:51:55
User entered empty.	Alisha Lutat (b) (4) (b) (4)	06 Oct 2020 18:21:19

US3572251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:20:40

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User entered 'MRNA-1273 OR PLACEBO'	System	06 Oct 2020 18:21:19

US3572251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:20:40

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:51:55
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 06Oct2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 10:57:03
Query 'Per GCL Lab Reconciliation: swab: Sample dated 06OCT2020 is present in GCL but data not present in EDC, please clarify or reconcile ' canceled (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 10:57:01
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 06Oct2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 12:15:07
User opened query 'Per GCL Lab Reconciliation: swab: Sample dated 06OCT2020 is present in GCL but data not present in EDC, please clarify or reconcile ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 21:15:38
User entered '6 Oct 2020'	Alisha Lutat (b) (4) (b) (4)	06 Oct 2020 18:21:19

US3572251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:20:40

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:51:55
User entered '13:23'	Alisha Lutat (b) (4) (b) (4)	06 Oct 2020 18:21:19

US3572251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:20:40

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User entered '6 Oct 2020 13:23'	System	06 Oct 2020 18:21:19

US3572251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:20:40

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:51:55
User entered 'Left Arm (LEFT ARM)'	Alisha Lutat (b) (4) (b) (4)	06 Oct 2020 18:21:19

US3572251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:20:40

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:51:55
User entered 'ONCE'	System	06 Oct 2020 18:21:19

US3572251

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:20:40

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User entered 'INTRAMUSCULAR'	System	06 Oct 2020 18:21:19

US3572251

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:52:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 23:37:24

US3572251

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:52:04
User entered '06 Oct 2020'	(b) (4), (b) (6)	15 Dec 2020 23:37:24

US3572251

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:52:04
User entered '12:37'	(b) (4), (b) (6)	15 Dec 2020 23:37:24

US3572251

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User entered '06 Oct 2020 12:37'	System	15 Dec 2020 23:37:24

US3572251

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:20:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:52:13
User entered '06 Oct 2020'	(b) (4), (b) (6)	15 Dec 2020 23:37:44

US3572251

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:20:40

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	15 Dec 2020 23:37:44

US3572251

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:20:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:52:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 23:37:44

US3572251

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:20:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:52:13
User entered '12:28'	(b) (4), (b) (6)	15 Dec 2020 23:37:44

US3572251

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:20:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User entered '06 Oct 2020 12:28'	System	15 Dec 2020 23:37:44

US3572251

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:20:40

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	15 Dec 2020 23:37:44

US3572251

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:20:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:52:13
User entered 'No (N)'	(b) (4), (b) (6)	15 Dec 2020 23:37:44

US3572251

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:20:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:52:13
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 23:37:44

US3572251

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:20:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User entered empty.	System	15 Dec 2020 23:37:44

US3572251

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 19:52:19
User entered 'Yes (Y)'	Jessica McDowell (b) (4) (b) (4)	13 Oct 2020 20:18:13

US3572251

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User entered 'I'	System	13 Oct 2020 20:18:13

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	06 Oct 2020 18:21:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T13:54:09', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'dbd0cd47-c424-450c-a1e8-4643785778c8' User entered 'Yes (Y)'	System	06 Oct 2020 18:54:27
	System	06 Oct 2020 18:54:27

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T13:54:14', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'dbd0cd47-c424-450c-a1e8-4643785778c8' User entered '97.3'	System	06 Oct 2020 18:54:27
	System	06 Oct 2020 18:54:27

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T13:54:18', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'dbd0cd47-c424-450c-a1e8-4643785778c8'	System	06 Oct 2020 18:54:27
User entered 'No (N)'	System	06 Oct 2020 18:54:27

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T13:54:22', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'dbd0cd47-c424-450c-a1e8-4643785778c8' User entered '06 Oct 2020 13:54'	System	06 Oct 2020 18:54:27
	System	06 Oct 2020 18:54:27

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '06 Oct 2020 13:43'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '06 Oct 2020 16:13'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	06 Oct 2020 18:21:19
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T17:08:28', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'c8ebf4ab-bd2c-4612-8263-570d3b36e098'	System	06 Oct 2020 22:08:46
User entered 'Yes (Y)'	System	06 Oct 2020 22:08:46

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T17:08:32', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'c8ebf4ab-bd2c-4612-8263-570d3b36e098' User entered '97.1'	System	06 Oct 2020 22:08:46
	System	06 Oct 2020 22:08:46

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T17:08:38', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'c8ebf4ab-bd2c-4612-8263-570d3b36e098'	System	06 Oct 2020 22:08:46
User entered 'No (N)'	System	06 Oct 2020 22:08:46

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T17:08:42', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'c8ebf4ab-bd2c-4612-8263-570d3b36e098' User entered '06 Oct 2020 17:08'	System	06 Oct 2020 22:08:46
	System	06 Oct 2020 22:08:46

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '06 Oct 2020 17:08'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	06 Oct 2020 18:21:19
User entered 'Day 2'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-07T18:00:56', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'ebe7783f-0cae-4ab3-a8ca-a55c6e91a5b0'	System	07 Oct 2020 23:01:09
User entered 'Yes (Y)'	System	07 Oct 2020 23:01:09

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-07T18:01:00', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'ebe7783f-0cae-4ab3-a8ca-a55c6e91a5b0' User entered '97.7'	System	07 Oct 2020 23:01:09
	System	07 Oct 2020 23:01:09

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-07T18:01:03', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'ebe7783f-0cae-4ab3-a8ca-a55c6e91a5b0'	System	07 Oct 2020 23:01:09
User entered 'No (N)'	System	07 Oct 2020 23:01:09

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-07T18:01:07', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'ebe7783f-0cae-4ab3-a8ca-a55c6e91a5b0' User entered '07 Oct 2020 18:01'	System	07 Oct 2020 23:01:09
	System	07 Oct 2020 23:01:09

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	06 Oct 2020 18:21:19
User entered 'Day 3'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-08T12:08:41', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'd6cdf07a-0de9-414a-80ab-b514a6d01bbc' User entered 'Yes (Y)'	System	08 Oct 2020 17:09:25
	System	08 Oct 2020 17:09:25

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-08T12:09:01', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'd6cdf07a-0de9-414a-80ab-b514a6d01bbc' User entered '96.7'	System	08 Oct 2020 17:09:25
	System	08 Oct 2020 17:09:25

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-08T12:09:10', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'd6cdf07a-0de9-414a-80ab-b514a6d01bbc' User entered 'No (N)'	System	08 Oct 2020 17:09:25
	System	08 Oct 2020 17:09:25

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-08T12:09:23', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'd6cdf07a-0de9-414a-80ab-b514a6d01bbc' User entered '08 Oct 2020 12:09'	System	08 Oct 2020 17:09:25
	System	08 Oct 2020 17:09:25

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	06 Oct 2020 18:21:19
User entered 'Day 4'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-09T16:32:23', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'c113af49-e22e-4b9e-a146-ca4b612ee62c' User entered 'Yes (Y)'	System	09 Oct 2020 21:32:35
	System	09 Oct 2020 21:32:35

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-09T16:32:26', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'c113af49-e22e-4b9e-a146-ca4b612ee62c' User entered '97.7'	System	09 Oct 2020 21:32:35
	System	09 Oct 2020 21:32:35

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-09T16:32:30', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'c113af49-e22e-4b9e-a146-ca4b612ee62c'	System	09 Oct 2020 21:32:35
User entered 'No (N)'	System	09 Oct 2020 21:32:35

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-09T16:32:32', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'c113af49-e22e-4b9e-a146-ca4b612ee62c' User entered '09 Oct 2020 16:32'	System	09 Oct 2020 21:32:35
	System	09 Oct 2020 21:32:35

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	06 Oct 2020 18:21:19
User entered 'Day 5'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-10T22:56:05', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '316f52c4-05a3-4fb4-8d2d-fd3f46475b2c' User entered 'Yes (Y)'	System	11 Oct 2020 03:56:20
	System	11 Oct 2020 03:56:20

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-10T22:56:10', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '316f52c4-05a3-4fb4-8d2d-fd3f46475b2c' User entered '97.7'	System	11 Oct 2020 03:56:20
	System	11 Oct 2020 03:56:20

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-10T22:56:15', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '316f52c4-05a3-4fb4-8d2d-fd3f46475b2c'	System	11 Oct 2020 03:56:20
User entered 'No (N)'	System	11 Oct 2020 03:56:20

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-10T22:56:18', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '316f52c4-05a3-4fb4-8d2d-fd3f46475b2c' User entered '10 Oct 2020 22:56'	System	11 Oct 2020 03:56:20
	System	11 Oct 2020 03:56:20

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	06 Oct 2020 18:21:19
User entered 'Day 6'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-11T12:37:38', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'e48abdde-7c69-4b2a-9be7-09991afd153e' User entered 'Yes (Y)'	System	11 Oct 2020 17:37:53
	System	11 Oct 2020 17:37:53

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-11T12:37:42', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'e48abdde-7c69-4b2a-9be7-09991afd153e' User entered '96.5'	System	11 Oct 2020 17:37:53
	System	11 Oct 2020 17:37:53

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-11T12:37:46', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'e48abdde-7c69-4b2a-9be7-09991afd153e' User entered 'No (N)'	System	11 Oct 2020 17:37:53
	System	11 Oct 2020 17:37:53

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-11T12:37:51', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'e48abdde-7c69-4b2a-9be7-09991afd153e' User entered '11 Oct 2020 12:37'	System	11 Oct 2020 17:37:53
	System	11 Oct 2020 17:37:53

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	06 Oct 2020 18:21:19
User entered 'Day 7'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-12T17:43:19', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '1cbbcbcea-b90d-4889-9847-cd1de6659a61' User entered 'Yes (Y)'	System	12 Oct 2020 22:43:43
	System	12 Oct 2020 22:43:43

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-12T17:43:27', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '1cbbcbcea-b90d-4889-9847-cd1de6659a61' User entered '96.7'	System	12 Oct 2020 22:43:43
	System	12 Oct 2020 22:43:43

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-12T17:43:32', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '1cbcbcea-b90d-4889-9847-cd1de6659a61'	System	12 Oct 2020 22:43:43
User entered 'No (N)'	System	12 Oct 2020 22:43:43

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-12T17:43:42', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '1cbbcbcea-b90d-4889-9847-cd1de6659a61' User entered '12 Oct 2020 17:43'	System	12 Oct 2020 22:43:43
	System	12 Oct 2020 22:43:43

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	06 Oct 2020 18:21:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T13:54:26', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '70f996eb-9115-4b75-afd5-50be8afa0437'	System	06 Oct 2020 18:54:51
User entered 'None (1)'	System	06 Oct 2020 18:54:51

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T13:54:30', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '70f996eb-9115-4b75-afd5-50be8afa0437'	System	06 Oct 2020 18:54:51
User entered 'No (N)'	System	06 Oct 2020 18:54:51

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T13:54:33', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '70f996eb-9115-4b75-afd5-50be8afa0437'	System	06 Oct 2020 18:54:51
User entered 'No (N)'	System	06 Oct 2020 18:54:51

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T13:54:42', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '70f996eb-9115-4b75-afd5-50be8afa0437'	System	06 Oct 2020 18:54:51
User entered 'None (1)'	System	06 Oct 2020 18:54:51

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T13:54:45', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '70f996eb-9115-4b75-afd5-50be8afa0437' User entered '06 Oct 2020 13:54'	System	06 Oct 2020 18:54:51
	System	06 Oct 2020 18:54:51

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '06 Oct 2020 13:43'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '06 Oct 2020 16:13'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	06 Oct 2020 18:21:19
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T17:08:49', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'ec94e04a-c287-4eb9-9cf3-cd7d958aa33e'	System	06 Oct 2020 22:09:20
User entered 'None (1)'	System	06 Oct 2020 22:09:20

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T17:08:53', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'ec94e04a-c287-4eb9-9cf3-cd7d958aa33e' User entered 'No (N)'	System	06 Oct 2020 22:09:20
	System	06 Oct 2020 22:09:20

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T17:08:58', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'ec94e04a-c287-4eb9-9cf3-cd7d958aa33e' User entered 'No (N)'	System	06 Oct 2020 22:09:20
	System	06 Oct 2020 22:09:20

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T17:09:13', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'ec94e04a-c287-4eb9-9cf3-cd7d958aa33e'	System	06 Oct 2020 22:09:20
User entered 'None (1)'	System	06 Oct 2020 22:09:20

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T17:09:17', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'ec94e04a-c287-4eb9-9cf3-cd7d958aa33e' User entered '06 Oct 2020 17:09'	System	06 Oct 2020 22:09:20
	System	06 Oct 2020 22:09:20

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '06 Oct 2020 17:08'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	06 Oct 2020 18:21:19
User entered 'Day 2'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-07T18:01:19', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'b2271188-7f2a-4e91-84ce-3c83d0fc63a5'	System	07 Oct 2020 23:01:54
User entered 'None (1)'	System	07 Oct 2020 23:01:54

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-07T18:01:38', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'b2271188-7f2a-4e91-84ce-3c83d0fc63a5'	System	07 Oct 2020 23:01:54
User entered 'No (N)'	System	07 Oct 2020 23:01:54

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-07T18:01:43', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'b2271188-7f2a-4e91-84ce-3c83d0fc63a5' User entered 'No (N)'	System	07 Oct 2020 23:01:54
	System	07 Oct 2020 23:01:54

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-07T18:01:47', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'b2271188-7f2a-4e91-84ce-3c83d0fc63a5'	System	07 Oct 2020 23:01:54
User entered 'None (1)'	System	07 Oct 2020 23:01:54

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-07T18:01:50', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'b2271188-7f2a-4e91-84ce-3c83d0fc63a5' User entered '07 Oct 2020 18:01'	System	07 Oct 2020 23:01:54
	System	07 Oct 2020 23:01:54

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	06 Oct 2020 18:21:19
User entered 'Day 3'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-08T12:09:29', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'bffe1fa3-aa0d-4d4b-94cf-84ee6a83c9cb'	System	08 Oct 2020 17:09:49
User entered 'None (1)'	System	08 Oct 2020 17:09:49

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-08T12:09:33', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'bffe1fa3-aa0d-4d4b-94cf-84ee6a83c9cb'	System	08 Oct 2020 17:09:49
User entered 'No (N)'	System	08 Oct 2020 17:09:49

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-08T12:09:39', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'bffe1fa3-aa0d-4d4b-94cf-84ee6a83c9cb'	System	08 Oct 2020 17:09:49
User entered 'No (N)'	System	08 Oct 2020 17:09:49

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-08T12:09:44', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'bffe1fa3-aa0d-4d4b-94cf-84ee6a83c9cb'	System	08 Oct 2020 17:09:49
User entered 'None (1)'	System	08 Oct 2020 17:09:49

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-08T12:09:46', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'bffe1fa3-aa0d-4d4b-94cf-84ee6a83c9cb' User entered '08 Oct 2020 12:09'	System	08 Oct 2020 17:09:49
	System	08 Oct 2020 17:09:49

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	06 Oct 2020 18:21:19
User entered 'Day 4'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-09T16:32:36', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'fda378b9-7721-49ff-9f60-a78f33d015ea'	System	09 Oct 2020 21:32:53
User entered 'None (1)'	System	09 Oct 2020 21:32:53

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-09T16:32:39', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'fda378b9-7721-49ff-9f60-a78f33d015ea' User entered 'No (N)'	System	09 Oct 2020 21:32:53
	System	09 Oct 2020 21:32:53

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-09T16:32:42', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'fda378b9-7721-49ff-9f60-a78f33d015ea' User entered 'No (N)'	System	09 Oct 2020 21:32:53
	System	09 Oct 2020 21:32:53

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-09T16:32:45', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'fda378b9-7721-49ff-9f60-a78f33d015ea'	System	09 Oct 2020 21:32:53
User entered 'None (1)'	System	09 Oct 2020 21:32:53

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-09T16:32:47', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'fda378b9-7721-49ff-9f60-a78f33d015ea' User entered '09 Oct 2020 16:32'	System	09 Oct 2020 21:32:53
	System	09 Oct 2020 21:32:53

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	06 Oct 2020 18:21:19
User entered 'Day 5'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-10T22:57:13', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'c4e4983a-b454-43ac-8108-18ed6b538953' User entered 'None (1)'	System	11 Oct 2020 03:57:36
	System	11 Oct 2020 03:57:36

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-10T22:57:08', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'c4e4983a-b454-43ac-8108-18ed6b538953'	System	11 Oct 2020 03:57:36
User entered 'No (N)'	System	11 Oct 2020 03:57:36

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-10T22:57:17', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'c4e4983a-b454-43ac-8108-18ed6b538953' User entered 'No (N)'	System	11 Oct 2020 03:57:36
	System	11 Oct 2020 03:57:36

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-10T22:57:22', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'c4e4983a-b454-43ac-8108-18ed6b538953' User entered 'None (1)'	System	11 Oct 2020 03:57:36
	System	11 Oct 2020 03:57:36

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-10T22:57:34', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'c4e4983a-b454-43ac-8108-18ed6b538953' User entered '10 Oct 2020 22:57'	System	11 Oct 2020 03:57:36
	System	11 Oct 2020 03:57:36

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	06 Oct 2020 18:21:19
User entered 'Day 6'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-11T12:37:56', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'cf36bf31-fb37-49af-a661-20e80b7f0e44'	System	11 Oct 2020 17:38:17
User entered 'None (1)'	System	11 Oct 2020 17:38:17

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-11T12:38:00', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'cf36bf31-fb37-49af-a661-20e80b7f0e44'	System	11 Oct 2020 17:38:17
User entered 'No (N)'	System	11 Oct 2020 17:38:17

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-11T12:38:07', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'cf36bf31-fb37-49af-a661-20e80b7f0e44'	System	11 Oct 2020 17:38:17
User entered 'No (N)'	System	11 Oct 2020 17:38:17

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-11T12:38:10', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'cf36bf31-fb37-49af-a661-20e80b7f0e44'	System	11 Oct 2020 17:38:17
User entered 'None (1)'	System	11 Oct 2020 17:38:17

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-11T12:38:14', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'cf36bf31-fb37-49af-a661-20e80b7f0e44'	System	11 Oct 2020 17:38:17
User entered '11 Oct 2020 12:38'	System	11 Oct 2020 17:38:17

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	06 Oct 2020 18:21:19
User entered 'Day 7'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-12T17:43:47', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '38104344-3ac8-43c3-8aa3-d27dd3005391'	System	12 Oct 2020 22:44:22
User entered 'None (1)'	System	12 Oct 2020 22:44:22

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-12T17:43:52', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '38104344-3ac8-43c3-8aa3-d27dd3005391'	System	12 Oct 2020 22:44:22
User entered 'No (N)'	System	12 Oct 2020 22:44:22

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-12T17:43:59', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '38104344-3ac8-43c3-8aa3-d27dd3005391'	System	12 Oct 2020 22:44:22
User entered 'No (N)'	System	12 Oct 2020 22:44:22

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-12T17:44:04', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '38104344-3ac8-43c3-8aa3-d27dd3005391'	System	12 Oct 2020 22:44:22
User entered 'None (1)'	System	12 Oct 2020 22:44:22

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-12T17:44:19', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '38104344-3ac8-43c3-8aa3-d27dd3005391' User entered '12 Oct 2020 17:44'	System	12 Oct 2020 22:44:22
	System	12 Oct 2020 22:44:22

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	06 Oct 2020 18:21:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T13:54:49', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'd6d8cdea-5bd3-4134-96bb-8df738b502d2' User entered 'None (0)'	System	06 Oct 2020 18:55:07
	System	06 Oct 2020 18:55:07

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T13:54:50', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'd6d8cdea-5bd3-4134-96bb-8df738b502d2' User entered 'None (0)'	System	06 Oct 2020 18:55:07
	System	06 Oct 2020 18:55:07

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T13:54:52', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'd6d8cdea-5bd3-4134-96bb-8df738b502d2' User entered 'None (0)'	System	06 Oct 2020 18:55:07
	System	06 Oct 2020 18:55:07

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T13:54:55', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'd6d8cdea-5bd3-4134-96bb-8df738b502d2' User entered 'None (0)'	System	06 Oct 2020 18:55:07
	System	06 Oct 2020 18:55:07

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T13:54:57', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'd6d8cdea-5bd3-4134-96bb-8df738b502d2' User entered 'None (0)'	System	06 Oct 2020 18:55:07
	System	06 Oct 2020 18:55:07

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T13:54:59', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'd6d8cdea-5bd3-4134-96bb-8df738b502d2' User entered 'None (0)'	System	06 Oct 2020 18:55:07
	System	06 Oct 2020 18:55:07

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

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)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T13:55:02', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'd6d8cdea-5bd3-4134-96bb-8df738b502d2'	System	06 Oct 2020 18:55:07
User entered 'No (N)'	System	06 Oct 2020 18:55:07

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T13:55:04', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'd6d8cdea-5bd3-4134-96bb-8df738b502d2' User entered '06 Oct 2020 13:55'	System	06 Oct 2020 18:55:07
	System	06 Oct 2020 18:55:07

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '06 Oct 2020 13:43'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '06 Oct 2020 16:13'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	06 Oct 2020 18:21:19
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T17:09:21', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'f9a4adca-aa7b-4489-a167-558d2e3f3393'	System	06 Oct 2020 22:10:01
User entered 'None (0)'	System	06 Oct 2020 22:10:01

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T17:09:24', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'f9a4adca-aa7b-4489-a167-558d2e3f3393' User entered 'None (0)'	System	06 Oct 2020 22:10:01
	System	06 Oct 2020 22:10:01

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T17:09:27', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'f9a4adca-aa7b-4489-a167-558d2e3f3393' User entered 'None (0)'	System	06 Oct 2020 22:10:01
	System	06 Oct 2020 22:10:01

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T17:09:30', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'f9a4adca-aa7b-4489-a167-558d2e3f3393' User entered 'None (0)'	System	06 Oct 2020 22:10:01
	System	06 Oct 2020 22:10:01

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T17:09:33', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'f9a4adca-aa7b-4489-a167-558d2e3f3393' User entered 'None (0)'	System	06 Oct 2020 22:10:01
	System	06 Oct 2020 22:10:01

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T17:09:49', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'f9a4adca-aa7b-4489-a167-558d2e3f3393' User entered 'None (0)'	System	06 Oct 2020 22:10:01
	System	06 Oct 2020 22:10:01

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

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)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T17:09:54', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'f9a4adca-aa7b-4489-a167-558d2e3f3393'	System	06 Oct 2020 22:10:01
User entered 'No (N)'	System	06 Oct 2020 22:10:01

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-06T17:09:59', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'f9a4adca-aa7b-4489-a167-558d2e3f3393' User entered '06 Oct 2020 17:09'	System	06 Oct 2020 22:10:01
	System	06 Oct 2020 22:10:01

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '06 Oct 2020 17:08'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	06 Oct 2020 18:21:19
User entered 'Day 2'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-07T18:01:54', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '62eb0a9f-1a93-4e6d-ab82-d20375988c4d' User entered 'None (0)'	System	07 Oct 2020 23:02:24
	System	07 Oct 2020 23:02:24

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-07T18:01:56', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '62eb0a9f-1a93-4e6d-ab82-d20375988c4d' User entered 'None (0)'	System	07 Oct 2020 23:02:24
	System	07 Oct 2020 23:02:24

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-07T18:01:59', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '62eb0a9f-1a93-4e6d-ab82-d20375988c4d' User entered 'None (0)'	System	07 Oct 2020 23:02:24
	System	07 Oct 2020 23:02:24

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-07T18:02:05', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '62eb0a9f-1a93-4e6d-ab82-d20375988c4d' User entered 'None (0)'	System	07 Oct 2020 23:02:24
	System	07 Oct 2020 23:02:24

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-07T18:02:08', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '62eb0a9f-1a93-4e6d-ab82-d20375988c4d' User entered 'None (0)'	System	07 Oct 2020 23:02:24
	System	07 Oct 2020 23:02:24

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-07T18:02:10', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '62eb0a9f-1a93-4e6d-ab82-d20375988c4d' User entered 'None (0)'	System	07 Oct 2020 23:02:24
	System	07 Oct 2020 23:02:24

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:40

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)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-07T18:02:13', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '62eb0a9f-1a93-4e6d-ab82-d20375988c4d' User entered 'No (N)'	System	07 Oct 2020 23:02:24
	System	07 Oct 2020 23:02:24

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-07T18:02:22', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '62eb0a9f-1a93-4e6d-ab82-d20375988c4d' User entered '07 Oct 2020 18:02'	System	07 Oct 2020 23:02:24
	System	07 Oct 2020 23:02:24

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	06 Oct 2020 18:21:19
User entered 'Day 3'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-08T12:09:51', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'b8b5d5d2-b50f-4379-bb0a-c219953c5f7c' User entered 'None (0)'	System	08 Oct 2020 17:10:37
	System	08 Oct 2020 17:10:37

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-08T12:09:59', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'b8b5d5d2-b50f-4379-bb0a-c219953c5f7c' User entered 'None (0)'	System	08 Oct 2020 17:10:37
	System	08 Oct 2020 17:10:37

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-08T12:10:04', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'b8b5d5d2-b50f-4379-bb0a-c219953c5f7c' User entered 'None (0)'	System	08 Oct 2020 17:10:37
	System	08 Oct 2020 17:10:37

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-08T12:10:15', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'b8b5d5d2-b50f-4379-bb0a-c219953c5f7c' User entered 'None (0)'	System	08 Oct 2020 17:10:37
	System	08 Oct 2020 17:10:37

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-08T12:10:22', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'b8b5d5d2-b50f-4379-bb0a-c219953c5f7c' User entered 'None (0)'	System	08 Oct 2020 17:10:37
	System	08 Oct 2020 17:10:37

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-08T12:10:26', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'b8b5d5d2-b50f-4379-bb0a-c219953c5f7c' User entered 'None (0)'	System	08 Oct 2020 17:10:37
	System	08 Oct 2020 17:10:37

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:40

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)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-08T12:10:31', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'b8b5d5d2-b50f-4379-bb0a-c219953c5f7c' User entered 'No (N)'	System	08 Oct 2020 17:10:37
	System	08 Oct 2020 17:10:37

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-08T12:10:34', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'b8b5d5d2-b50f-4379-bb0a-c219953c5f7c' User entered '08 Oct 2020 12:10'	System	08 Oct 2020 17:10:37
	System	08 Oct 2020 17:10:37

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	06 Oct 2020 18:21:19
User entered 'Day 4'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-09T16:32:52', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '91d1b7c2-6ca6-46ef-95d2-ddfc48ef3a24' User entered 'None (0)'	System	09 Oct 2020 21:33:12
	System	09 Oct 2020 21:33:12

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-09T16:32:55', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '91d1b7c2-6ca6-46ef-95d2-ddfc48ef3a24' User entered 'None (0)'	System	09 Oct 2020 21:33:12
	System	09 Oct 2020 21:33:12

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-09T16:32:58', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '91d1b7c2-6ca6-46ef-95d2-ddfc48ef3a24' User entered 'None (0)'	System	09 Oct 2020 21:33:12
	System	09 Oct 2020 21:33:12

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-09T16:33:00', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '91d1b7c2-6ca6-46ef-95d2-ddfc48ef3a24' User entered 'None (0)'	System	09 Oct 2020 21:33:12
	System	09 Oct 2020 21:33:12

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-09T16:33:02', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '91d1b7c2-6ca6-46ef-95d2-ddfc48ef3a24' User entered 'None (0)'	System	09 Oct 2020 21:33:12
	System	09 Oct 2020 21:33:12

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-09T16:33:05', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '91d1b7c2-6ca6-46ef-95d2-ddfc48ef3a24' User entered 'None (0)'	System	09 Oct 2020 21:33:12
	System	09 Oct 2020 21:33:12

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:40

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)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-09T16:33:07', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '91d1b7c2-6ca6-46ef-95d2-ddfc48ef3a24'	System	09 Oct 2020 21:33:12
User entered 'No (N)'	System	09 Oct 2020 21:33:12

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-09T16:33:09', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '91d1b7c2-6ca6-46ef-95d2-ddfc48ef3a24' User entered '09 Oct 2020 16:33'	System	09 Oct 2020 21:33:12
	System	09 Oct 2020 21:33:12

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	06 Oct 2020 18:21:19
User entered 'Day 5'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-10T22:57:40', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '9686741e-391b-4872-8fc8-5d39e2db894b' User entered 'None (0)'	System	11 Oct 2020 03:57:59
	System	11 Oct 2020 03:57:59

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-10T22:57:42', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '9686741e-391b-4872-8fc8-5d39e2db894b' User entered 'None (0)'	System	11 Oct 2020 03:57:59
	System	11 Oct 2020 03:57:59

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-10T22:57:46', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '9686741e-391b-4872-8fc8-5d39e2db894b' User entered 'None (0)'	System	11 Oct 2020 03:57:59
	System	11 Oct 2020 03:57:59

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-10T22:57:49', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '9686741e-391b-4872-8fc8-5d39e2db894b' User entered 'None (0)'	System	11 Oct 2020 03:57:59
	System	11 Oct 2020 03:57:59

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-10T22:57:50', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '9686741e-391b-4872-8fc8-5d39e2db894b' User entered 'None (0)'	System	11 Oct 2020 03:57:59
	System	11 Oct 2020 03:57:59

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-10T22:57:52', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '9686741e-391b-4872-8fc8-5d39e2db894b' User entered 'None (0)'	System	11 Oct 2020 03:57:59
	System	11 Oct 2020 03:57:59

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:40

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)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-10T22:57:55', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '9686741e-391b-4872-8fc8-5d39e2db894b' User entered 'No (N)'	System	11 Oct 2020 03:57:59
	System	11 Oct 2020 03:57:59

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-10T22:57:58', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '9686741e-391b-4872-8fc8-5d39e2db894b' User entered '10 Oct 2020 22:57'	System	11 Oct 2020 03:57:59
	System	11 Oct 2020 03:57:59

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	06 Oct 2020 18:21:19
User entered 'Day 6'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-11T12:38:19', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '4d329d85-ba13-46b7-807a-b77f1dd5605b' User entered 'None (0)'	System	11 Oct 2020 17:38:41
	System	11 Oct 2020 17:38:41

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-11T12:38:21', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '4d329d85-ba13-46b7-807a-b77f1dd5605b' User entered 'None (0)'	System	11 Oct 2020 17:38:41
	System	11 Oct 2020 17:38:41

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-11T12:38:24', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '4d329d85-ba13-46b7-807a-b77f1dd5605b' User entered 'None (0)'	System	11 Oct 2020 17:38:41
	System	11 Oct 2020 17:38:41

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-11T12:38:27', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '4d329d85-ba13-46b7-807a-b77f1dd5605b' User entered 'None (0)'	System	11 Oct 2020 17:38:41
	System	11 Oct 2020 17:38:41

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-11T12:38:30', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '4d329d85-ba13-46b7-807a-b77f1dd5605b' User entered 'None (0)'	System	11 Oct 2020 17:38:41
	System	11 Oct 2020 17:38:41

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-11T12:38:32', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '4d329d85-ba13-46b7-807a-b77f1dd5605b' User entered 'None (0)'	System	11 Oct 2020 17:38:41
	System	11 Oct 2020 17:38:41

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:40

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)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-11T12:38:36', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '4d329d85-ba13-46b7-807a-b77f1dd5605b' User entered 'No (N)'	System	11 Oct 2020 17:38:41
	System	11 Oct 2020 17:38:41

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-11T12:38:38', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '4d329d85-ba13-46b7-807a-b77f1dd5605b' User entered '11 Oct 2020 12:38'	System	11 Oct 2020 17:38:41
	System	11 Oct 2020 17:38:41

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
Data entry locked.	System	06 Oct 2020 18:21:19
User entered 'Day 7'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-12T17:44:23', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '2ff9f6c6-a31f-4dad-a893-469c087bfa44'	System	12 Oct 2020 22:45:22
User entered 'None (0)'	System	12 Oct 2020 22:45:22

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-12T17:44:55', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '2ff9f6c6-a31f-4dad-a893-469c087bfa44'	System	12 Oct 2020 22:45:22
User entered 'None (0)'	System	12 Oct 2020 22:45:22

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-12T17:44:58', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '2ff9f6c6-a31f-4dad-a893-469c087bfa44' User entered 'None (0)'	System	12 Oct 2020 22:45:22
	System	12 Oct 2020 22:45:22

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-12T17:45:06', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '2ff9f6c6-a31f-4dad-a893-469c087bfa44'	System	12 Oct 2020 22:45:22
User entered 'None (0)'	System	12 Oct 2020 22:45:22

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-12T17:45:08', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '2ff9f6c6-a31f-4dad-a893-469c087bfa44'	System	12 Oct 2020 22:45:22
User entered 'None (0)'	System	12 Oct 2020 22:45:22

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-12T17:45:12', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '2ff9f6c6-a31f-4dad-a893-469c087bfa44'	System	12 Oct 2020 22:45:22
User entered 'None (0)'	System	12 Oct 2020 22:45:22

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:40

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)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-12T17:45:17', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '2ff9f6c6-a31f-4dad-a893-469c087bfa44'	System	12 Oct 2020 22:45:22
User entered 'No (N)'	System	12 Oct 2020 22:45:22

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-10-12T17:45:20', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '2ff9f6c6-a31f-4dad-a893-469c087bfa44'	System	12 Oct 2020 22:45:22
User entered '12 Oct 2020 17:45'	System	12 Oct 2020 22:45:22

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 18:21:19

US3572251

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:20:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:55:38
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 18:21:19

US3572251

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Dec 2020 03:09:48
User entered 'Yes (Y)'	Jessica McDowell (b) (4) (b) (4)	13 Oct 2020 20:18:28

US3572251

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Dec 2020 03:09:48
User entered '13 Oct 2020'	Jessica McDowell (b) (4) (b) (4)	13 Oct 2020 20:18:28

US3572251

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Dec 2020 03:09:48
User entered 'Contact Made (CONTACT MADE)'	Jessica McDowell (b) (4) (b) (4)	13 Oct 2020 20:18:28

US3572251

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Dec 2020 03:09:48
User entered empty.	Jessica Mcdowell (b) (4) (b) (4)	13 Oct 2020 20:18:28

US3572251

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Dec 2020 03:09:54
User entered 'Yes (Y)'	Jessica McDowell (b) (4) (b) (4)	13 Oct 2020 20:24:58

US3572251

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User entered 'l'	System	13 Oct 2020 20:24:58

US3572251

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Dec 2020 03:10:05
User entered 'Yes (Y)'	Jessica McDowell (b) (4) (b) (4)	20 Oct 2020 22:27:53

US3572251

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Dec 2020 03:10:05
User entered '20 Oct 2020'	Jessica McDowell (b) (4) (b) (4)	20 Oct 2020 22:27:53

US3572251

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Dec 2020 03:10:05
User entered 'Contact Made (CONTACT MADE)'	Jessica McDowell (b) (4) (b) (4)	20 Oct 2020 22:27:53

US3572251

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Dec 2020 03:10:05
User entered empty.	Jessica Mcdowell (b) (4) (b) (4)	20 Oct 2020 22:27:53

US3572251

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Dec 2020 03:10:10
User entered 'Yes (Y)'	Jessica McDowell (b) (4) (b) (4)	20 Oct 2020 22:27:57

US3572251

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User entered 'l'	System	20 Oct 2020 22:27:57

US3572251

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Dec 2020 03:10:19
User entered 'Yes (Y)'	Jessica McDowell (b) (4) (b) (4)	27 Oct 2020 21:47:38

US3572251

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Dec 2020 03:10:19
User entered '27 Oct 2020'	Jessica McDowell (b) (4) (b) (4)	27 Oct 2020 21:47:38

US3572251

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Dec 2020 03:10:19
User entered 'Contact Made (CONTACT MADE)'	Jessica McDowell (b) (4) (b) (4)	27 Oct 2020 21:47:38

US3572251

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Dec 2020 03:10:19
User entered empty.	Jessica Mcdowell (b) (4) (b) (4)	27 Oct 2020 21:47:38

US3572251

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:35
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	11 Dec 2020 03:10:25
User entered 'Yes (Y)'	Jessica McDowell (b) (4) (b) (4)	27 Oct 2020 21:47:45

US3572251

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User entered 'l'	System	27 Oct 2020 21:47:45

US3572251

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 20:19:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Dec 2020 23:51:08

US3572251

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:40

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 20:19:29
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	18 Dec 2020 07:57:09
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'Subject had missed several scheduled appointments' (Site from System).	(b) (4), (b) (6)	16 Dec 2020 23:51:30
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	16 Dec 2020 23:51:08
User entered '11 Dec 2020'	(b) (4), (b) (6)	16 Dec 2020 23:51:08

US3572251

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 20:19:29
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Dec 2020 23:51:08

US3572251

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:40

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User entered 'VISIT3'	System	16 Dec 2020 23:51:08

US3572251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 20:19:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Dec 2020 23:52:30

US3572251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 20:19:49
User entered '11 Dec 2020'	(b) (4), (b) (6)	16 Dec 2020 23:52:30

US3572251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 20:19:49
User entered '12:15'	(b) (4), (b) (6)	16 Dec 2020 23:52:30

US3572251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User entered '11 Dec 2020 12:15'	System	16 Dec 2020 23:52:30

US3572251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 20:19:49
User entered '97.7' F	(b) (4), (b) (6)	16 Dec 2020 23:52:30

US3572251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 20:19:49
User entered 'Other (Other)'	(b) (4), (b) (6)	16 Dec 2020 23:52:30

US3572251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 20:19:49
User entered 'TEMPORAL'	(b) (4), (b) (6)	16 Dec 2020 23:52:30

US3572251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 20:19:49
User entered '56'	(b) (4), (b) (6)	16 Dec 2020 23:52:30

US3572251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User entered 'bpm'	System	16 Dec 2020 23:52:30

US3572251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 20:19:49
User entered '20'	(b) (4), (b) (6)	16 Dec 2020 23:52:30

US3572251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User entered 'breaths/min'	System	16 Dec 2020 23:52:30

US3572251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 20:19:49
User entered '150'	(b) (4), (b) (6)	16 Dec 2020 23:52:30

US3572251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User entered 'mmHg'	System	16 Dec 2020 23:52:30

US3572251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 20:19:49
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	18 Dec 2020 03:06:58
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS SUBJECT TOOK CONMED FOR HYPERTENSION AND HOUR BEFORE VISIT' (Site from System).	(b) (4), (b) (6)	16 Dec 2020 23:52:58
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		16 Dec 2020 23:52:30
User entered '102'	(b) (4), (b) (6)	16 Dec 2020 23:52:30

US3572251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User entered 'mmHg'	System	16 Dec 2020 23:52:30

US3572251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16

US3572251

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16

US3572251

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:44:28
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User closed query 'Per CDM: Visit 3 Day 57 and Illness Visit Day 1 are both dated 11Dec2020. However, the data on the Physical Examination forms and other forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review, reconcile and complete necessary forms to match the data in these two visits. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 03:15:48
Query 'Per CDM: Visit 3 Day 57 and Illness Visit Day 1 are both dated 11Dec2020. However, the data on the Physical Examination forms and other forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review, reconcile and complete necessary forms to match the data in these two visits. Thank you.' answered with 'PE performed on 11DEC20 per source' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 06:15:33
DataPoint Un-verified.	(b) (4), (b) (6)	25 Mar 2021 06:15:14
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 06:15:14
User opened query 'Per CDM: Visit 3 Day 57 and Illness Visit Day 1 are both dated 11Dec2020. However, the data on the Physical Examination forms and other forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review, reconcile and complete necessary forms to match the data in these two visits. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Mar 2021 11:54:18

US3572251

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Query 'Per CDM: Visit 3 Day 57 and Illness Visit Day 1 are both dated 23Nov2020. However, the data on the Physical Examination forms and other forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review, reconcile and complete necessary forms to match the data in these two visits. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	20 Mar 2021 11:53:13
User opened query 'Per CDM: Visit 3 Day 57 and Illness Visit Day 1 are both dated 23Nov2020. However, the data on the Physical Examination forms and other forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review, reconcile and complete necessary forms to match the data in these two visits. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Mar 2021 11:53:08
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 20:20:06
User entered 'No (N)'	(b) (4), (b) (6)	16 Dec 2020 23:53:03

US3572251

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:44:28
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 06:15:14
User entered '11 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 06:15:14
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 20:20:06
User entered empty.	(b) (4), (b) (6)	16 Dec 2020 23:53:03

US3572251

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 20:20:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Dec 2020 23:53:38

US3572251

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 20:20:11
User entered '11 Dec 2020'	(b) (4), (b) (6)	16 Dec 2020 23:53:38

US3572251

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:40

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 20:20:11
User entered '12:20'	(b) (4), (b) (6)	16 Dec 2020 23:53:38

US3572251

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User entered '11 Dec 2020 12:20'	System	16 Dec 2020 23:53:38

US3572251

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:18:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	07 Jan 2021 20:20:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Dec 2020 16:59:13

US3572251

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User entered 'I'	System	02 Dec 2020 16:59:13

US3572251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:56:38
Data entry locked.	System	10 Sep 2020 17:23:37
User entered 'Day 64'	System	10 Sep 2020 17:23:37

US3572251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:56:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-11-10T08:41:27', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '3fe832af-1197-47ee-908b-b5afca25126d'	System	10 Nov 2020 14:41:44
User entered 'No (N)'	System	10 Nov 2020 14:41:44

US3572251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:56:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-11-10T08:41:38', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '3fe832af-1197-47ee-908b-b5afca25126d'	System	10 Nov 2020 14:41:44
User entered 'No (N)'	System	10 Nov 2020 14:41:44

US3572251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:56:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-11-10T08:41:42', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '3fe832af-1197-47ee-908b-b5afca25126d' User entered '10 Nov 2020 08:41:42'	System	10 Nov 2020 14:41:44
	System	10 Nov 2020 14:41:44

US3572251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:56:38
Data entry locked.	System	10 Sep 2020 17:23:37
User entered '10 Nov 2020 00:01'	System	10 Sep 2020 17:23:37

US3572251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:56:38
Data entry locked.	System	10 Sep 2020 17:23:37
User entered '14 Nov 2020 23:59'	System	10 Sep 2020 17:23:37

US3572251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:56:38
Data entry locked.	System	10 Sep 2020 17:23:37
User entered 'Day 71'	System	10 Sep 2020 17:23:37

US3572251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:56:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-11-17T06:38:19', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '540e306f-3162-4f98-859a-6c4f6966c628'	System	17 Nov 2020 12:38:37
User entered 'No (N)'	System	17 Nov 2020 12:38:37

US3572251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:56:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-11-17T06:38:28', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '540e306f-3162-4f98-859a-6c4f6966c628'	System	17 Nov 2020 12:38:37
User entered 'No (N)'	System	17 Nov 2020 12:38:37

US3572251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:56:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-11-17T06:38:34', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '540e306f-3162-4f98-859a-6c4f6966c628' User entered '17 Nov 2020 06:38:34'	System	17 Nov 2020 12:38:37
	System	17 Nov 2020 12:38:37

US3572251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:56:38
Data entry locked.	System	10 Sep 2020 17:23:37
User entered '17 Nov 2020 00:01'	System	10 Sep 2020 17:23:37

US3572251

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:56:38
Data entry locked.	System	10 Sep 2020 17:23:37
User entered '21 Nov 2020 23:59'	System	10 Sep 2020 17:23:37

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-11-28T00:07:01', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'fc623519-fb76-44bd-b0c8-65827fabd1f1'	System	28 Nov 2020 06:07:12
User entered 'No (N)'	System	28 Nov 2020 06:07:12

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-11-28T00:07:05', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'fc623519-fb76-44bd-b0c8-65827fabd1f1'	System	28 Nov 2020 06:07:12
User entered 'No (N)'	System	28 Nov 2020 06:07:12

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-11-28T00:07:09', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'fc623519-fb76-44bd-b0c8-65827fabd1f1'	System	28 Nov 2020 06:07:12
User entered '28 Nov 2020 00:07:09'	System	28 Nov 2020 06:07:12

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-12-05T00:06:45', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'a816053f-e3a7-4168-b40a-58f69700621f'	System	05 Dec 2020 06:07:32
User entered 'Yes (Y)'	System	05 Dec 2020 06:07:32

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-12-05T00:06:52', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'a816053f-e3a7-4168-b40a-58f69700621f' User entered 'No (N)'	System	05 Dec 2020 06:07:32
	System	05 Dec 2020 06:07:32

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-12-05T00:06:59', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'a816053f-e3a7-4168-b40a-58f69700621f' User entered 'No (N)'	System	05 Dec 2020 06:07:32
	System	05 Dec 2020 06:07:32

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-12-05T00:07:23', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'a816053f-e3a7-4168-b40a-58f69700621f'	System	05 Dec 2020 06:07:32
User entered 'No (N)'	System	05 Dec 2020 06:07:32

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-12-05T00:07:25', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'a816053f-e3a7-4168-b40a-58f69700621f' User entered '05 Dec 2020 00:07:25'	System	05 Dec 2020 06:07:32
	System	05 Dec 2020 06:07:32

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-12-12T01:54:40', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '396d3fa0-9ed7-4c6b-866b-c9b0e2884a8d'	System	12 Dec 2020 07:54:57
User entered 'No (N)'	System	12 Dec 2020 07:54:57

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-12-12T01:54:48', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '396d3fa0-9ed7-4c6b-866b-c9b0e2884a8d'	System	12 Dec 2020 07:54:57
User entered 'No (N)'	System	12 Dec 2020 07:54:57

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-12-12T01:54:53', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '396d3fa0-9ed7-4c6b-866b-c9b0e2884a8d' User entered '12 Dec 2020 01:54:53'	System	12 Dec 2020 07:54:57
	System	12 Dec 2020 07:54:57

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-12-19T10:06:03', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '7f86293b-34a2-491e-b7e6-ce5e884e04b9'	System	19 Dec 2020 16:06:12
User entered 'No (N)'	System	19 Dec 2020 16:06:12

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-12-19T10:05:58', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '7f86293b-34a2-491e-b7e6-ce5e884e04b9'	System	19 Dec 2020 16:06:12
User entered 'No (N)'	System	19 Dec 2020 16:06:12

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A0EEF4F3-FC41-4428-9B6C-8C01C44D8C8E)', Time: '2020-12-19T10:06:07', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '7f86293b-34a2-491e-b7e6-ce5e884e04b9' User entered '19 Dec 2020 10:06:07'	System	19 Dec 2020 16:06:12
	System	19 Dec 2020 16:06:12

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-02-02T14:50:38', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '875f1e4b-08d5-4c9c-8479-49d11dcabe1b'	System	02 Feb 2021 20:52:00
User entered 'No (N)'	System	02 Feb 2021 20:52:00

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-02-02T14:51:27', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '875f1e4b-08d5-4c9c-8479-49d11dcabe1b'	System	02 Feb 2021 20:52:00
User entered 'No (N)'	System	02 Feb 2021 20:52:00

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-02-02T14:51:55', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '875f1e4b-08d5-4c9c-8479-49d11dcabe1b' User entered '02 Feb 2021 14:51:55'	System	02 Feb 2021 20:52:00
	System	02 Feb 2021 20:52:00

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-02-06T07:48:49', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '217868ff-ce58-4571-b453-51979b6549cc'	System	06 Feb 2021 13:49:51
User entered 'No (N)'	System	06 Feb 2021 13:49:51

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-02-06T07:49:45', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '217868ff-ce58-4571-b453-51979b6549cc'	System	06 Feb 2021 13:49:51
User entered 'No (N)'	System	06 Feb 2021 13:49:51

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-02-06T07:49:48', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '217868ff-ce58-4571-b453-51979b6549cc' User entered '06 Feb 2021 07:49:48'	System	06 Feb 2021 13:49:51
	System	06 Feb 2021 13:49:51

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-02-13T00:01:23', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'ac190da6-c3ac-4d34-b7d9-64db89f7b48c'	System	13 Feb 2021 06:02:21
User entered 'Yes (Y)'	System	13 Feb 2021 06:02:21

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-02-13T00:01:27', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'ac190da6-c3ac-4d34-b7d9-64db89f7b48c'	System	13 Feb 2021 06:02:21
User entered 'Yes (Y)'	System	13 Feb 2021 06:02:21

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-02-13T00:01:30', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'ac190da6-c3ac-4d34-b7d9-64db89f7b48c'	System	13 Feb 2021 06:02:21
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Feb 2021 06:02:21

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-02-13T00:01:36', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'ac190da6-c3ac-4d34-b7d9-64db89f7b48c'	System	13 Feb 2021 06:02:21
User entered 'No (N)'	System	13 Feb 2021 06:02:21

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-02-13T00:01:44', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'ac190da6-c3ac-4d34-b7d9-64db89f7b48c'	System	13 Feb 2021 06:02:21
User entered 'No (N)'	System	13 Feb 2021 06:02:21

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-02-13T00:01:58', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'ac190da6-c3ac-4d34-b7d9-64db89f7b48c' User entered '13 Feb 2021 00:01:58'	System	13 Feb 2021 06:02:21
	System	13 Feb 2021 06:02:21

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-02-22T11:43:24', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '6627213b-5803-4d82-9235-f20f22d3a607'	System	22 Feb 2021 17:43:50
User entered 'No (N)'	System	22 Feb 2021 17:43:50

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-02-22T11:43:44', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '6627213b-5803-4d82-9235-f20f22d3a607'	System	22 Feb 2021 17:43:50
User entered 'No (N)'	System	22 Feb 2021 17:43:50

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-02-22T11:43:48', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '6627213b-5803-4d82-9235-f20f22d3a607' User entered '22 Feb 2021 11:43:48'	System	22 Feb 2021 17:43:50
	System	22 Feb 2021 17:43:50

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-02-27T06:25:27-06:00', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'dfb5084d-a36d-49dd-94ec-aa3354d60376'	System	01 Mar 2021 17:17:48
User entered 'No (N)'	System	01 Mar 2021 17:17:48

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-02-27T06:25:32-06:00', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'dfb5084d-a36d-49dd-94ec-aa3354d60376'	System	01 Mar 2021 17:17:48
User entered 'No (N)'	System	01 Mar 2021 17:17:48

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-02-27T06:25:35-06:00', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'dfb5084d-a36d-49dd-94ec-aa3354d60376' User entered '27 Feb 2021 12:25:35'	System	01 Mar 2021 17:17:48
	System	01 Mar 2021 17:17:48

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-03-06T13:41:22-06:00', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'cd25a117-a1cd-41cf-99dc-043c83ee1f74'	System	06 Mar 2021 19:41:39
User entered 'No (N)'	System	06 Mar 2021 19:41:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-03-06T13:41:28-06:00', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'cd25a117-a1cd-41cf-99dc-043c83ee1f74'	System	06 Mar 2021 19:41:39
User entered 'No (N)'	System	06 Mar 2021 19:41:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-03-06T13:41:31-06:00', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: 'cd25a117-a1cd-41cf-99dc-043c83ee1f74'	System	06 Mar 2021 19:41:39
User entered '06 Mar 2021 13:41:31'	System	06 Mar 2021 19:41:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-03-13T04:22:25-06:00', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '03727251-2f05-4744-a26e-12adf2f8b157'	System	13 Mar 2021 10:22:39
User entered 'No (N)'	System	13 Mar 2021 10:22:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-03-13T04:22:30-06:00', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '03727251-2f05-4744-a26e-12adf2f8b157'	System	13 Mar 2021 10:22:39
User entered 'No (N)'	System	13 Mar 2021 10:22:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-03-13T04:22:33-06:00', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '03727251-2f05-4744-a26e-12adf2f8b157'	System	13 Mar 2021 10:22:39
User entered '13 Mar 2021 04:22:33'	System	13 Mar 2021 10:22:39

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-03-20T00:03:59-05:00', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '7c379896-47d4-444f-b1c7-1cf785437b48'	System	20 Mar 2021 05:04:54
User entered 'Yes (Y)'	System	20 Mar 2021 05:04:54

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-03-20T00:04:10-05:00', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '7c379896-47d4-444f-b1c7-1cf785437b48'	System	20 Mar 2021 05:04:54
User entered 'No (N)'	System	20 Mar 2021 05:04:54

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-03-20T00:04:21-05:00', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '7c379896-47d4-444f-b1c7-1cf785437b48'	System	20 Mar 2021 05:04:54
User entered 'No (N)'	System	20 Mar 2021 05:04:54

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-03-20T00:04:31-05:00', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '7c379896-47d4-444f-b1c7-1cf785437b48'	System	20 Mar 2021 05:04:54
User entered 'Yes (Y)'	System	20 Mar 2021 05:04:54

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-03-20T00:04:38-05:00', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '7c379896-47d4-444f-b1c7-1cf785437b48'	System	20 Mar 2021 05:04:54
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Mar 2021 05:04:54

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-03-20T00:04:42-05:00', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '7c379896-47d4-444f-b1c7-1cf785437b48'	System	20 Mar 2021 05:04:54
User entered '20 Mar 2021 00:04:42'	System	20 Mar 2021 05:04:54

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-03-27T20:55:17-05:00', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '096b4b18-18e2-420e-986f-5f6530f1040b'	System	28 Mar 2021 01:57:13
User entered 'Yes (Y)'	System	28 Mar 2021 01:57:13

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-03-27T20:56:20-05:00', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '096b4b18-18e2-420e-986f-5f6530f1040b'	System	28 Mar 2021 01:57:13
User entered 'Yes (Y)'	System	28 Mar 2021 01:57:13

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-03-27T20:56:27-05:00', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '096b4b18-18e2-420e-986f-5f6530f1040b'	System	28 Mar 2021 01:57:13
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Mar 2021 01:57:13

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-03-27T20:56:37-05:00', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '096b4b18-18e2-420e-986f-5f6530f1040b'	System	28 Mar 2021 01:57:13
User entered 'No (N)'	System	28 Mar 2021 01:57:13

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-03-27T20:56:50-05:00', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '096b4b18-18e2-420e-986f-5f6530f1040b'	System	28 Mar 2021 01:57:13
User entered 'Yes (Y)'	System	28 Mar 2021 01:57:13

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-03-27T20:56:56-05:00', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '096b4b18-18e2-420e-986f-5f6530f1040b'	System	28 Mar 2021 01:57:13
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Mar 2021 01:57:13

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-03-27T20:57:00-05:00', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '096b4b18-18e2-420e-986f-5f6530f1040b'	System	28 Mar 2021 01:57:13
User entered '27 Mar 2021 20:57:00'	System	28 Mar 2021 01:57:13

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 07:10:33

US3572251

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:20:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:46:20
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:10:33
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 07:10:33

US3572251

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:20:40

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:19:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-03-01T11:05:04-06:00', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '97539c18-4623-4fec-b5f3-ac7e092c98d7'	System	01 Mar 2021 17:18:12
User entered 'No (N)'	System	01 Mar 2021 17:18:12

US3572251

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:20:40

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:19:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76AC5DDB-80B6-4216-8FCF-C954C86ED0DE)', Time: '2021-03-01T11:05:07-06:00', User OID: 'PatientReportedOutcome (US3572251)', ODM File OID: '97539c18-4623-4fec-b5f3-ac7e092c98d7' User entered '01 Mar 2021 11:05:07'	System	01 Mar 2021 17:18:12
	System	01 Mar 2021 17:18:12

US3572251

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:21:24
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	16 Feb 2021 17:23:51
User entered 'Yes (Y)'	Jessica McDowell (b) (4) (b) (4)	02 Dec 2020 16:59:27

US3572251

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:21:24
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	16 Feb 2021 17:23:51
User entered '2 Dec 2020'	Jessica McDowell (b) (4) (b) (4)	02 Dec 2020 16:59:27

US3572251

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:21:24
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	16 Feb 2021 17:23:51
User entered 'Contact Made (CONTACT MADE)'	Jessica McDowell (b) (4) (b) (4)	02 Dec 2020 16:59:27

US3572251

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:21:24
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	16 Feb 2021 17:23:51
User entered empty.	Jessica McDowell (b) (4) (b) (4)	02 Dec 2020 16:59:27

US3572251

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:21:24
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	16 Feb 2021 17:23:48
User entered 'Yes (Y)'	Jessica McDowell (b) (4) (b) (4)	02 Dec 2020 16:59:31

US3572251

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:16
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14DEC2020 and 16DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	25 Apr 2021 21:10:19
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14DEC2020 and 16DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 09:20:46
User entered 'I'	System	02 Dec 2020 16:59:31

US3572251

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:27
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:54:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User closed query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 02-Feb-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 11:21:21
' (Site from DM). Query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 02-Feb-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.	(b) (4), (b) (6)	23 Feb 2021 03:43:33
' answered with 'data for this sample collected 02FEB21 at PDV entered into EDC' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 02-Feb-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.	(b) (4), (b) (6)	19 Feb 2021 06:57:19
' (Site from DM). User entered 'Yes (Y)'	Jessica McDowell (b) (4) (b) (4)	05 Jan 2021 15:29:53

US3572251

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:27
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:54:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '5 Jan 2021'	(b) (4) Jessica McDowell (b) (4) (b) (4)	05 Jan 2021 15:29:53

US3572251

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:27
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:54:25
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'Contact Made (CONTACT MADE)'	Jessica McDowell (b) (4) (b) (4)	05 Jan 2021 15:29:53

US3572251

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:27
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:54:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	05 Jan 2021 15:29:53

US3572251

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:27
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:54:31
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'Yes (Y)'	Jessica McDowell (b) (4) (b) (4)	05 Jan 2021 15:29:57

US3572251

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:27
User entered 'l'	System	05 Jan 2021 15:29:57

US3572251

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	04 Mar 2021 15:50:39
User entered 'Yes (Y)'	Jessica McDowell (b) (4)	01 Feb 2021 18:06:50

US3572251

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	04 Mar 2021 15:50:39
User entered '1 Feb 2021'	Jessica McDowell (b) (4)	01 Feb 2021 18:06:50

US3572251

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	04 Mar 2021 15:50:39
User entered 'Contact Made (CONTACT MADE)'	Jessica McDowell (b) (4)	01 Feb 2021 18:06:50

US3572251

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	04 Mar 2021 15:50:39
User entered empty.	Jessica McDowell (b) (4)	01 Feb 2021 18:06:50

US3572251

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	04 Mar 2021 15:50:42
User entered 'Yes (Y)'	Jessica McDowell (b) (4)	01 Feb 2021 18:06:54

US3572251

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:27
User entered 'l'	System	01 Feb 2021 18:06:54

US3572251

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:27
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:55:02
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'Yes (Y)'	Jessica Mcdowell (b) (4) (b) (4)	03 Mar 2021 03:03:11

US3572251

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:27
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:55:02
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered '2 Mar 2021'	Jessica McDowell (b) (4) (b) (4)	03 Mar 2021 03:03:11

US3572251

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:27
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:55:02
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'Contact Made (CONTACT MADE)'	Jessica McDowell (b) (4) (b) (4)	03 Mar 2021 03:03:11

US3572251

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:20:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:27
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:55:02
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	03 Mar 2021 03:03:11

US3572251

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:27
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:55:08
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	03 Mar 2021 03:03:16

US3572251

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:20:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:49:27
User entered 'l'	System	03 Mar 2021 03:03:16

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:20:40

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:20
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User closed query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re- Query: As per the response "Source verified; All data for Illness Day 1 entered in EDC ", however there is no 11 DEC 2020 SARS-CoV-2 serum sample updated in the corresponding illness visit EDC page, please verify and update the data as needed, else clarify. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 10:00:49
Query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re- Query: As per the response "Source verified; All data for Illness Day 1 entered in EDC ", however there is no 11 DEC 2020 SARS-CoV-2 serum sample updated in the corresponding illness visit EDC page, please verify and update the data as needed, else clarify. Thank you. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 20:11:21
User closed query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample with a Collection Date of 11DEC2020, however this sample is missing in EDC. Please complete the COVID Diagnostic Test form within this folder, as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 09:33:10
User closed query 'Per CDM: It appears that both initial start date of symptoms and Contact date are the same (11Dec 2020). Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 06:59:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:20:40

[Date of Contact](#)

Audit	User	Time (GMT)
User opened query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: As per the response "Source verified; All data for Illness Day 1 entered in EDC ", however there is no 11 DEC 2020 SARS-CoV-2 serum sample updated in the corresponding illness visit EDC page, please verify and update the data as needed, else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 11:59:50
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 11 DEC 2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the sample has been collected and update the details under appropriate visit or provide clarification, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 11:51:20
Query 'Per CDM: It appears that both initial start date of symptoms and Contact date are the same (11Dec 2020). Please review and reconcile.' answered with 'Dates confirmed correct' (Site from DM).	Alisha Lutat (b) (4)	16 Feb 2021 20:01:51
Query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample with a Collection Date of 11DEC2020, however this sample is missing in EDC. Please complete the COVID Diagnostic Test form within this folder, as appropriate.' answered with 'All data has been updated in EDC for visit on 11Dec2020' (Site from DM).	Alisha Lutat (b) (4)	16 Feb 2021 20:01:35
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 11 DEC 2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the sample has been collected and update the details under appropriate visit or provide clarification, thank you.' answered with 'Source verified; All data for Illness Day 1 entered in EDC ' (Site from DM).	Alisha Lutat (b) (4)	16 Feb 2021 19:55:09
User opened query 'Per CDM: It appears that both initial start date of symptoms and Contact date are the same (11Dec 2020). Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 16:23:18

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:20:40

[Date of Contact](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample with a Collection Date of 11DEC2020, however this sample is missing in EDC. Please complete the COVID Diagnostic Test form within this folder, as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 18:25:39
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 11 DEC 2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the sample has been collected and update the details under appropriate visit or provide clarification, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 06:15:45
User entered '11 Dec 2020'	Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:25

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:20:40

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:20
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '12:00'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:25

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:20:40

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '11 Dec 2020 12:00'	System	15 Dec 2020 19:32:25

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:20:40

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:20
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:25

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:20:40

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:20
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Yes (Y)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:25

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:20:40

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Day 1 (Day 1)'	(b) (4) Jessica McDowell (b) (4)	15 Dec 2020 19:32:38

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:20:40

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '11 Dec 2020'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:38

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:20:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User closed query 'Per CDM: It appears complete data is not recorded for days 1 and 2. If assessment is not done, Update this field accordingly and consider to update temperature as Not Done. Please review and reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 06:15:50
Query 'Per CDM: It appears complete data is not recorded for days 1 and 2. If assessment is not done, Update this field accordingly and consider to update temperature as Not Done. Please review and reconcile.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 20:21:31
User entered '1' reason for change: Per Query Resolution	(b) (4), (b) (6)	25 Feb 2021 20:21:16
User opened query 'Per CDM: It appears complete data is not recorded for days 1 and 2. If assessment is not done, Update this field accordingly and consider to update temperature as Not Done. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 06:48:38
User entered '0'	Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:38

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:20:40

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User closed query 'Per CDM : It appears data is missing for days 1 and 2. Please review and update accordingly.' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	18 Feb 2021 06:44:26
Query 'Per CDM : It appears data is missing for days 1 and 2. Please review and update accordingly.'	Alisha Lutat (b) (4)	16 Feb 2021 19:56:49
answered with 'Data updated to 'ND" (Site from DM).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Alisha Lutat (b) (4)	16 Feb 2021 19:56:40
	(b) (4)	
User opened query 'Per CDM : It appears data is missing for days 1 and 2. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 16:24:27
User entered empty.	Jessica McDowell (b) (4)	15 Dec 2020 19:32:38
	(b) (4)	

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:20:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '%'	System	16 Feb 2021 19:56:40
User entered empty.	System	15 Dec 2020 19:32:38

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:20:40

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:38

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:20:40

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:38

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:20:40

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:38

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:20:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered empty.	Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:38

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:20:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:38

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:20:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:38

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:20:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered empty.	Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:38

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:20:40

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:38

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:20:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:38

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:20:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:38

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:20:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:38

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:20:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:38

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:20:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered empty.	Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:38

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:20:40

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:38

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:20:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:38

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:20:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:38

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:20:40

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:38

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:20:40

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Day 2 (Day 2)'	(b) (4) Jessica McDowell (b) (4)	15 Dec 2020 19:32:47

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:20:40

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '12 Dec 2020'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:47

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:20:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '0'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:47

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:20:40

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
User entered empty.	Alisha Lutat (b) (4)	16 Feb 2021 19:56:58
	(b) (4)	
	Jessica Mcdowell (b) (4)	15 Dec 2020 19:32:47
	(b) (4)	

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:20:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '%'	System	16 Feb 2021 19:56:58
User entered empty.	System	15 Dec 2020 19:32:47

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:20:40

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:47

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:20:40

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:47

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:20:40

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:47

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:20:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:47

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:20:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:47

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:20:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:47

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:20:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered empty.	Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:47

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:20:40

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:47

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:20:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:47

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:20:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:47

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:20:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:47

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:20:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:47

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:20:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:47

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:20:40

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:47

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:20:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:47

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:20:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:47

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:20:40

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:32:47

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:20:40

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Day 3 (Day 3)'	(b) (4) Jessica McDowell (b) (4)	15 Dec 2020 19:34:49

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:20:40

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '13 Dec 2020'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:34:49

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:20:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '0'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:34:49

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:20:40

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '96'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:34:49

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:20:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '%'	System	15 Dec 2020 19:34:49

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:20:40

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '98.0' F	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:34:49

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:20:40

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:34:49

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:20:40

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:34:49

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:20:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:34:49

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:20:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:34:49

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:20:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:34:49

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:20:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:34:49

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:20:40

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:34:49

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:20:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:34:49

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:20:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:34:49

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:20:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:34:49

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:20:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Mild (Mild)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:34:49

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:20:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Mild (Mild)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:34:49

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:20:40

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:34:49

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:20:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	Jessica Mcdowell (b) (4) (b) (4)	15 Dec 2020 19:34:49

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:20:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:34:49

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:20:40

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:34:49

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:20:40

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Day 4 (Day 4)'	(b) (4) Jessica McDowell (b) (4)	15 Dec 2020 19:35:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:20:40

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '14 Dec 2020'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:35:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:20:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '0'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:35:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:20:40

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '96'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:35:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:20:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '%'	System	15 Dec 2020 19:35:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:20:40

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '97.7' F	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:35:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:20:40

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:35:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:20:40

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:35:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:20:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:35:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:20:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:35:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:20:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:35:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:20:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:35:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:20:40

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:35:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:20:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:35:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:20:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:35:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:20:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:35:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:20:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:35:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:20:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:35:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:20:40

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:35:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:20:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:35:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:20:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:35:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:20:40

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:35:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:20:40

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Day 5 (Day 5)'	(b) (4) Jessica McDowell (b) (4)	15 Dec 2020 19:36:55

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:20:40

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '15 Dec 2020'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:36:55

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:20:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '0'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:36:55

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:20:40

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '98'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:36:55

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:20:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '%'	System	15 Dec 2020 19:36:55

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:20:40

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '97.8' F	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:36:55

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:20:40

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:36:55

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:20:40

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:36:55

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:20:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:36:55

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:20:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:36:55

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:20:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:36:55

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:20:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:36:55

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:20:40

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:36:55

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:20:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:36:55

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:20:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:36:55

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:20:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:36:55

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:20:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:36:55

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:20:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:36:55

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:20:40

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:36:55

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:20:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:36:55

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:20:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:36:55

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:20:40

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	15 Dec 2020 19:36:55

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:20:40

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Day 6 (Day 6)'	(b) (4) Jessica McDowell (b) (4)	16 Dec 2020 19:38:32

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:20:40

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '16 Dec 2020'	(b) (4) Jessica McDowell (b) (4) (b) (4)	16 Dec 2020 19:38:32

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:20:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '0'	(b) (4) Jessica McDowell (b) (4) (b) (4)	16 Dec 2020 19:38:32

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:20:40

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '97'	(b) (4) Jessica McDowell (b) (4) (b) (4)	16 Dec 2020 19:38:32

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:20:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '%'	System	16 Dec 2020 19:38:32

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:20:40

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '97.0' F	(b) (4) Jessica McDowell (b) (4) (b) (4)	16 Dec 2020 19:38:32

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:20:40

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	16 Dec 2020 19:38:32

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:20:40

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	16 Dec 2020 19:38:32

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:20:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	16 Dec 2020 19:38:32

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:20:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	16 Dec 2020 19:38:32

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:20:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	16 Dec 2020 19:38:32

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:20:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	Jessica Mcdowell (b) (4) (b) (4)	16 Dec 2020 19:38:32

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:20:40

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	16 Dec 2020 19:38:32

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:20:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	16 Dec 2020 19:38:32

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:20:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	16 Dec 2020 19:38:32

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:20:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	16 Dec 2020 19:38:32

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:20:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	Jessica Mcdowell (b) (4) (b) (4)	16 Dec 2020 19:38:32

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:20:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	Jessica McDowell (b) (4) (b) (4)	16 Dec 2020 19:38:32

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:20:40

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	16 Dec 2020 19:38:32

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:20:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	16 Dec 2020 19:38:32

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:20:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	16 Dec 2020 19:38:32

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:20:40

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	16 Dec 2020 19:38:32

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:20:40

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Day 7 (Day 7)'	(b) (4) Jessica McDowell (b) (4)	17 Dec 2020 19:24:45

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:20:40

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '17 Dec 2020'	(b) (4) Jessica McDowell (b) (4) (b) (4)	17 Dec 2020 19:24:45

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:20:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '0'	(b) (4) Jessica McDowell (b) (4) (b) (4)	17 Dec 2020 19:24:45

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:20:40

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '95'	(b) (4) Jessica McDowell (b) (4) (b) (4)	17 Dec 2020 19:24:45

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:20:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '%'	System	17 Dec 2020 19:24:45

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:20:40

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '97.6' F	(b) (4) Jessica McDowell (b) (4) (b) (4)	17 Dec 2020 19:24:45

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:20:40

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	17 Dec 2020 19:24:45

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:20:40

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	17 Dec 2020 19:24:45

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:20:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	17 Dec 2020 19:24:45

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:20:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	17 Dec 2020 19:24:45

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:20:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	17 Dec 2020 19:24:45

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:20:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	Jessica Mcdowell (b) (4) (b) (4)	17 Dec 2020 19:24:45

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:20:40

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	Jessica McDowell (b) (4) (b) (4)	17 Dec 2020 19:24:45

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:20:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	17 Dec 2020 19:24:45

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:20:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	Jessica Mcdowell (b) (4) (b) (4)	17 Dec 2020 19:24:45

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:20:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	17 Dec 2020 19:24:45

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:20:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	17 Dec 2020 19:24:45

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:20:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	17 Dec 2020 19:24:45

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:20:40

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	17 Dec 2020 19:24:45

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:20:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	17 Dec 2020 19:24:45

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:20:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	17 Dec 2020 19:24:45

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:20:40

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	17 Dec 2020 19:24:45

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:20:40

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Day 8 (Day 8)'	(b) (4) Jessica McDowell (b) (4)	18 Dec 2020 19:54:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:20:40

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '18 Dec 2020'	(b) (4) Jessica McDowell (b) (4) (b) (4)	18 Dec 2020 19:54:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:20:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '0'	(b) (4) Jessica McDowell (b) (4) (b) (4)	18 Dec 2020 19:54:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:20:40

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '95'	(b) (4) Jessica McDowell (b) (4) (b) (4)	18 Dec 2020 19:54:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:20:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '%'	System	18 Dec 2020 19:54:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:20:40

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '97.5' F	(b) (4) Jessica McDowell (b) (4) (b) (4)	18 Dec 2020 19:54:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:20:40

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	18 Dec 2020 19:54:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:20:40

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	18 Dec 2020 19:54:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:20:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	18 Dec 2020 19:54:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:20:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	18 Dec 2020 19:54:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:20:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	18 Dec 2020 19:54:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:20:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	Jessica McDowell (b) (4) (b) (4)	18 Dec 2020 19:54:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:20:40

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	18 Dec 2020 19:54:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:20:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	18 Dec 2020 19:54:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:20:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	18 Dec 2020 19:54:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:20:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	18 Dec 2020 19:54:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:20:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	18 Dec 2020 19:54:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:20:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	Jessica McDowell (b) (4) (b) (4)	18 Dec 2020 19:54:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:20:40

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	18 Dec 2020 19:54:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:20:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	18 Dec 2020 19:54:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:20:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	18 Dec 2020 19:54:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:20:40

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	18 Dec 2020 19:54:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:20:40

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Day 9 (Day 9)'	(b) (4) Jessica McDowell (b) (4)	19 Dec 2020 23:59:20

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:20:40

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '19 Dec 2020'	(b) (4) Jessica McDowell (b) (4) (b) (4)	19 Dec 2020 23:59:20

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:20:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '0'	(b) (4) Jessica McDowell (b) (4) (b) (4)	19 Dec 2020 23:59:20

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:20:40

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '97'	(b) (4) Jessica McDowell (b) (4) (b) (4)	19 Dec 2020 23:59:20

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:20:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '%'	System	19 Dec 2020 23:59:20

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:20:40

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '98.1' F	(b) (4) Jessica McDowell (b) (4) (b) (4)	19 Dec 2020 23:59:20

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:20:40

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	19 Dec 2020 23:59:20

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:20:40

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	19 Dec 2020 23:59:20

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:20:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	19 Dec 2020 23:59:20

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:20:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	19 Dec 2020 23:59:20

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:20:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	19 Dec 2020 23:59:20

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:20:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	19 Dec 2020 23:59:20

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:20:40

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	19 Dec 2020 23:59:20

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:20:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	19 Dec 2020 23:59:20

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:20:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	19 Dec 2020 23:59:20

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:20:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	19 Dec 2020 23:59:20

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:20:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	19 Dec 2020 23:59:20

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:20:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	19 Dec 2020 23:59:20

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:20:40

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	19 Dec 2020 23:59:20

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:20:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	19 Dec 2020 23:59:20

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:20:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	19 Dec 2020 23:59:20

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:20:40

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	19 Dec 2020 23:59:20

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:20:40

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Day 10 (Day 10)'	(b) (4) Jessica McDowell (b) (4)	20 Dec 2020 23:12:01

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:20:40

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '20 Dec 2020'	(b) (4) Jessica McDowell (b) (4) (b) (4)	20 Dec 2020 23:12:01

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:20:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '0'	(b) (4) Jessica McDowell (b) (4) (b) (4)	20 Dec 2020 23:12:01

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:20:40

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '97'	(b) (4) Jessica McDowell (b) (4) (b) (4)	20 Dec 2020 23:12:01

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:20:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '%'	System	20 Dec 2020 23:12:01

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:20:40

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '97.6' F	(b) (4) Jessica McDowell (b) (4) (b) (4)	20 Dec 2020 23:12:01

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:20:40

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	20 Dec 2020 23:12:01

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:20:40

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	20 Dec 2020 23:12:01

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:20:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	20 Dec 2020 23:12:01

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:20:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	20 Dec 2020 23:12:01

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:20:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	20 Dec 2020 23:12:01

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:20:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	Jessica Mcdowell (b) (4) (b) (4)	20 Dec 2020 23:12:01

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:20:40

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	20 Dec 2020 23:12:01

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:20:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	20 Dec 2020 23:12:01

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:20:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	20 Dec 2020 23:12:01

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:20:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	20 Dec 2020 23:12:01

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:20:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	20 Dec 2020 23:12:01

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:20:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	20 Dec 2020 23:12:01

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:20:40

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	20 Dec 2020 23:12:01

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:20:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	20 Dec 2020 23:12:01

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:20:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	20 Dec 2020 23:12:01

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:20:40

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	20 Dec 2020 23:12:01

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:20:40

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Day 11 (Day 11)'	(b) (4) Jessica McDowell (b) (4)	21 Dec 2020 22:22:00

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:20:40

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '21 Dec 2020'	(b) (4) Jessica McDowell (b) (4) (b) (4)	21 Dec 2020 22:22:00

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:20:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '0'	(b) (4) Jessica McDowell (b) (4) (b) (4)	21 Dec 2020 22:22:00

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:20:40

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '97'	(b) (4) Jessica McDowell (b) (4) (b) (4)	21 Dec 2020 22:22:00

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:20:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '%'	System	21 Dec 2020 22:22:00

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:20:40

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '97.6' F	(b) (4) Jessica McDowell (b) (4) (b) (4)	21 Dec 2020 22:22:00

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:20:40

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	21 Dec 2020 22:22:00

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:20:40

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	21 Dec 2020 22:22:00

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:20:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	21 Dec 2020 22:22:00

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:20:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	21 Dec 2020 22:22:00

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:20:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	21 Dec 2020 22:22:00

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:20:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	21 Dec 2020 22:22:00

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:20:40

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4)	21 Dec 2020 22:22:00

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:20:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	21 Dec 2020 22:22:00

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:20:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	21 Dec 2020 22:22:00

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:20:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	21 Dec 2020 22:22:00

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:20:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	21 Dec 2020 22:22:00

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:20:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	21 Dec 2020 22:22:00

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:20:40

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	21 Dec 2020 22:22:00

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:20:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	21 Dec 2020 22:22:00

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:20:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	21 Dec 2020 22:22:00

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:20:40

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	21 Dec 2020 22:22:00

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:20:40

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Day 12 (Day 12)'	(b) (4) Jessica McDowell (b) (4)	22 Dec 2020 18:46:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:20:40

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '22 Dec 2020'	(b) (4) Jessica McDowell (b) (4) (b) (4)	22 Dec 2020 18:46:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:20:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '0'	(b) (4) Jessica McDowell (b) (4) (b) (4)	22 Dec 2020 18:46:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:20:40

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '96'	(b) (4) Jessica McDowell (b) (4) (b) (4)	22 Dec 2020 18:46:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:20:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '%'	System	22 Dec 2020 18:46:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:20:40

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '97.1' F	(b) (4) Jessica McDowell (b) (4) (b) (4)	22 Dec 2020 18:46:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:20:40

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	22 Dec 2020 18:46:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:20:40

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	22 Dec 2020 18:46:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:20:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	22 Dec 2020 18:46:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:20:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	22 Dec 2020 18:46:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:20:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	22 Dec 2020 18:46:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:20:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	22 Dec 2020 18:46:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:20:40

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	22 Dec 2020 18:46:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:20:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	22 Dec 2020 18:46:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:20:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	22 Dec 2020 18:46:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:20:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	22 Dec 2020 18:46:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:20:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	22 Dec 2020 18:46:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:20:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	22 Dec 2020 18:46:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:20:40

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	22 Dec 2020 18:46:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:20:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	22 Dec 2020 18:46:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:20:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	22 Dec 2020 18:46:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:20:40

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	22 Dec 2020 18:46:51

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:20:40

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Day 13 (Day 13)'	(b) (4) Jessica McDowell (b) (4)	23 Dec 2020 22:21:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:20:40

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '23 Dec 2020'	(b) (4) Jessica McDowell (b) (4) (b) (4)	23 Dec 2020 22:21:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:20:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '0'	(b) (4) Jessica McDowell (b) (4) (b) (4)	23 Dec 2020 22:21:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:20:40

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '96'	(b) (4) Jessica McDowell (b) (4) (b) (4)	23 Dec 2020 22:21:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:20:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '%'	System	23 Dec 2020 22:21:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:20:40

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '97.1' F	(b) (4) Jessica McDowell (b) (4) (b) (4)	23 Dec 2020 22:21:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:20:40

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	23 Dec 2020 22:21:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:20:40

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	23 Dec 2020 22:21:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:20:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	23 Dec 2020 22:21:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:20:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	23 Dec 2020 22:21:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:20:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	23 Dec 2020 22:21:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:20:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	Jessica McDowell (b) (4) (b) (4)	23 Dec 2020 22:21:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:20:40

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	23 Dec 2020 22:21:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:20:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	23 Dec 2020 22:21:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:20:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	23 Dec 2020 22:21:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:20:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	23 Dec 2020 22:21:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:20:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4)	23 Dec 2020 22:21:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:20:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	23 Dec 2020 22:21:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:20:40

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	23 Dec 2020 22:21:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:20:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	23 Dec 2020 22:21:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:20:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	23 Dec 2020 22:21:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:20:40

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'None (None)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	23 Dec 2020 22:21:26

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:20:40

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:31
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '11 Dec 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	16 Feb 2021 19:55:36

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:20:40

[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 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:31
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	16 Feb 2021 19:55:36

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:20:40

[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 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:31
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	16 Feb 2021 19:55:36

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:20:40

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14DEC2020 and 16DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 05:34:27
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14DEC2020 and 16DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'updated as per query resolution' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 16:37:10
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14DEC2020 and 16DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	25 Apr 2021 21:11:11
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:31
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '11 Dec 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	16 Feb 2021 19:55:36

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:20:40

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:31
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Alisha Lutat (b) (4)	16 Feb 2021 19:55:36

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:20:40

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:31
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	16 Feb 2021 19:55:36

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:20:40

[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 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:31
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	16 Feb 2021 19:55:36

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:20:40

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:31
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	16 Feb 2021 19:55:36

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:20:40

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:31
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	16 Feb 2021 19:55:36

US3572251

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:20:40

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '0'	System	16 Feb 2021 19:55:36

US3572251

Folder: Covid-19 Assessment 24 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:20:40

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:07
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '24 Sep 2020'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:16:16

US3572251

Folder: Covid-19 Assessment 24 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:20:40

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:07
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered '09:00'	Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:16:16

US3572251

Folder: Covid-19 Assessment 24 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:20:40

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '24 Sep 2020 09:00'	System	24 Sep 2020 14:16:16

US3572251

Folder: Covid-19 Assessment 24 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:20:40

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:07
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'Safety Call (Safety Call)'	Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:16:16

US3572251

Folder: Covid-19 Assessment 24 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:20:40

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:07
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)'	Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:16:16

US3572251

Folder: Covid-19 Assessment 24 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:20:40

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:12
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 11-DEC-2020 is reported under Illness Visit Day 1 in PPD portal; however, data is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating Swab data in the COVID Diagnostic form. Else clarify.	(b) (4) (u) (4), (b) (6)	23 Feb 2021 09:32:13
' (Site from DM). Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 11-DEC-2020 is reported under Illness Visit Day 1 in PPD portal; however, data is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating Swab data in the COVID Diagnostic form. Else clarify.	Alisha Lutat (b) (4) (b) (4)	16 Feb 2021 20:02:30
' answered with 'All data for Illness Day1 on 11Dec2020 has been updated in EDC ' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 11-DEC-2020 is reported under Illness Visit Day 1 in PPD portal; however, data is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating Swab data in the COVID Diagnostic form. Else clarify.	(b) (4), (b) (6)	15 Dec 2020 11:56:59
' (Site from DM). User entered 'Yes (Y)'	Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:16:23

US3572251

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:20:40

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	27 Feb 2021 00:25:23

US3572251

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:20:40

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:58:24
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:59
DataPoint Un-verified.	(b) (4) (u) (4), (b) (6)	26 Apr 2021 16:36:18
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 16:36:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 16:36:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:59:42
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	27 Feb 2021 00:25:23

US3572251

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:20:40

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:58:24
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:59
DataPoint Un-verified.	(b) (4) (u) (4), (b) (6)	26 Apr 2021 16:36:18
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 16:36:18
User entered '14 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 16:36:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:59:42
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) (u) (4), (b) (6)	27 Feb 2021 00:25:23

US3572251

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:20:40

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	27 Feb 2021 00:25:23

US3572251

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:20:40

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:58:24
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:59
DataPoint Un-verified.	(b) (4) (u) (4), (b) (6)	26 Apr 2021 16:36:18
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 16:36:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 16:36:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:59:42
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	27 Feb 2021 00:25:23

US3572251

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:20:40

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:58:24
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:59
DataPoint Un-verified.	(b) (4) (u) (4), (b) (6)	26 Apr 2021 16:36:18
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 16:36:18
User entered '16 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 16:36:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:59:42
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) (u) (4), (b) (6)	27 Feb 2021 00:25:23

US3572251

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:20:40

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	27 Feb 2021 00:25:23

US3572251

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:20:40

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:58:24
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:59
DataPoint Un-verified.	(b) (4) (u) (4), (b) (6)	26 Apr 2021 16:36:18
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 16:36:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 16:36:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:59:42
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	27 Feb 2021 00:25:23

US3572251

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:20:40

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:58:24
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:59
DataPoint Un-verified.	(b) (4) (u) (4), (b) (6)	26 Apr 2021 16:36:18
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 16:36:18
User entered '18 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 16:36:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:59:42
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) (u) (4), (b) (6)	27 Feb 2021 00:25:23

US3572251

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:20:40

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	27 Feb 2021 00:25:23

US3572251

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:20:40

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:58:24
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:59
DataPoint Un-verified.	(b) (4) (u) (4), (b) (6)	26 Apr 2021 16:36:18
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 16:36:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 16:36:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:59:42
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	27 Feb 2021 00:25:23

US3572251

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:20:40

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:58:24
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:59
DataPoint Un-verified.	(b) (4) (u) (4), (b) (6)	26 Apr 2021 16:36:18
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 16:36:18
User entered '20 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 16:36:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:59:42
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) (u) (4), (b) (6)	27 Feb 2021 00:25:23

US3572251

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:20:40

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	27 Feb 2021 00:25:23

US3572251

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:20:40

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:58:24
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:59
DataPoint Un-verified.	(b) (4) (u) (4), (b) (6)	26 Apr 2021 16:36:18
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 16:36:18
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 16:36:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:59:42
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	27 Feb 2021 00:25:23

US3572251

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:20:40

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:59:42
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Feb 2021 00:25:23

US3572251

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:20:40

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	27 Feb 2021 00:25:23

US3572251

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:20:40

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:58:24
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:59
DataPoint Un-verified.	(b) (4) (u) (4), (b) (6)	26 Apr 2021 16:36:18
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 16:36:18
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 16:36:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:59:42
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	27 Feb 2021 00:25:23

US3572251

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:20:40

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:59:42
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Feb 2021 00:25:23

US3572251

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:20:40

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	27 Feb 2021 00:25:23

US3572251

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:20:40

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 17:58:24
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:59
DataPoint Un-verified.	(b) (4) (u) (4), (b) (6)	26 Apr 2021 16:36:18
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 16:36:18
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 16:36:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:59:42
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	27 Feb 2021 00:25:23

US3572251

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:20:40

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:59:42
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Feb 2021 00:25:23

US3572251

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:49
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	16 Feb 2021 19:57:35

US3572251

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:49
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '11 Dec 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	16 Feb 2021 19:57:35

US3572251

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:58:49
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Clinic (Clinic)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	16 Feb 2021 19:57:35

US3572251

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:20:40

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered 'SICKD1'	System	16 Feb 2021 19:57:35

US3572251

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:59:04
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	16 Feb 2021 19:59:23

US3572251

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:59:04
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	16 Feb 2021 19:59:42
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	16 Feb 2021 19:59:42
User entered '11 Dec 2020' reason for change: Data Entry Error	Alisha Lutat (b) (4)	16 Feb 2021 19:59:42
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	16 Feb 2021 19:59:23
User entered '15 Dec 2020'	Alisha Lutat (b) (4)	16 Feb 2021 19:59:23

US3572251

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:59:04
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '12:15'	(b) (4) Alisha Lutat (b) (4) (b) (4)	16 Feb 2021 19:59:23

US3572251

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '11 Dec 2020 12:15'	System	16 Feb 2021 19:59:42
User entered '15 Dec 2020 12:15'	System	16 Feb 2021 19:59:23

US3572251

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:59:04
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	16 Feb 2021 19:59:23
DataPoint set to visible.	(b) (4) System	16 Feb 2021 19:57:35

US3572251

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:59:04
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '232.0' lb	(b) (4) Alisha Lutat (b) (4)	16 Feb 2021 19:59:23
DataPoint set to visible.	(b) (4) System	16 Feb 2021 19:57:35

US3572251

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:59:04
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '97.7' F	(b) (4) Alisha Lutat (b) (4) (b) (4)	16 Feb 2021 19:59:23

US3572251

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:59:04
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Other (Other)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	16 Feb 2021 19:59:23

US3572251

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:59:04
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Temporal'	(b) (4) Alisha Lutat (b) (4) (b) (4)	16 Feb 2021 19:59:23

US3572251

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:59:04
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '56'	(b) (4) Alisha Lutat (b) (4) (b) (4)	16 Feb 2021 19:59:23

US3572251

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered 'bpm'	System	16 Feb 2021 19:59:23

US3572251

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:59:04
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '20'	(b) (4) Alisha Lutat (b) (4) (b) (4)	16 Feb 2021 19:59:23

US3572251

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered 'breaths/min'	System	16 Feb 2021 19:59:23

US3572251

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:59:04
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '150'	(b) (4) Alisha Lutat (b) (4) (b) (4)	16 Feb 2021 19:59:23

US3572251

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered 'mmHg'	System	16 Feb 2021 19:59:23

US3572251

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:59:04
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User closed query 'Per CDM: Response noted. Please indicate if the value is CS/NCS and report as AE, if appropriate.	(b) (4) (u) (4), (b) (6)	01 Mar 2021 10:41:19
' (Site from DM). Query 'Per CDM: Response noted. Please indicate if the value is CS/NCS and report as AE, if appropriate.	(b) (4), (b) (6)	25 Feb 2021 20:22:33
' answered with 'NCS' (Site from DM). User opened query 'Per CDM: Response noted. Please indicate if the value is CS/NCS and report as AE, if appropriate.	(b) (4), (b) (6)	18 Feb 2021 10:42:32
' (Site from DM). Query 'Per CDM: Response noted. Please Please indicate if the value is CS/NCS and report as AE, if appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 10:42:00
User opened query 'Per CDM: Response noted. Please Please indicate if the value is CS/NCS and report as AE, if appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 10:40:55
Query 'Per CDM: Thanks for the response. Out of range values are evaluated for clinical significance. Please indicate if CS/NCS and report as AE, if appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 10:39:15
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	18 Feb 2021 07:04:56
User opened query 'Per CDM: Thanks for the response. Out of range values are evaluated for clinical significance. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 07:04:49

US3572251

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Diastolic BP will be evaluated by PI' (Site from System).	Alisha Lutat (b) (4)	16 Feb 2021 20:00:01
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		16 Feb 2021 19:59:23
User entered '102'	Alisha Lutat (b) (4)	16 Feb 2021 19:59:23

US3572251

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered 'mmHg'	System	16 Feb 2021 19:59:23

US3572251

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:20:40

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:59:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Feb 2021 00:22:28

US3572251

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:20:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:59:17
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	27 Feb 2021 00:22:28

US3572251

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 08:20:40

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:59:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 20:09:38

US3572251

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 08:20:40

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:59:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '11 Dec 2020'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 20:09:38

US3572251

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

Form: Visit Date

Generated On: 10 Jun 2021 08:20:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:52:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:49:12
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 03:43:48

US3572251

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

Form: Visit Date

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:52:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:49:12
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '02 Feb 2021'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 03:43:48

US3572251

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

Form: Visit Date

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:52:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:49:12
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Clinic (Clinic)'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 03:43:48

US3572251

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

Form: Visit Date

Generated On: 10 Jun 2021 08:20:40

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:52:06
User entered 'UNBLND_DECIDE'	System	23 Feb 2021 03:43:48

US3572251

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

Form: Unblinding

Generated On: 10 Jun 2021 08:20:40

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:52:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:49:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '02 Feb 2021'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 03:44:09

US3572251

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

Form: Unblinding

Generated On: 10 Jun 2021 08:20:40

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:52:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:57:19

US3572251

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

Form: Unblinding

Generated On: 10 Jun 2021 08:20:40

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:52:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:49:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 03:44:09

US3572251

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

Form: Unblinding

Generated On: 10 Jun 2021 08:20:40

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:52:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:57:19

US3572251

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

Form: Unblinding

Generated On: 10 Jun 2021 08:20:40

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:52:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:49:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 03:44:09

US3572251

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

Form: Unblinding

Generated On: 10 Jun 2021 08:20:40

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:52:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:49:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 03:44:09

US3572251

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

Form: Unblinding

Generated On: 10 Jun 2021 08:20:40

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:52:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:49:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 03:44:09

US3572251

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

Form: Unblinding

Generated On: 10 Jun 2021 08:20:40

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:52:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:49:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 03:44:09

US3572251

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

Form: Unblinding

Generated On: 10 Jun 2021 08:20:40

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:52:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:49:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 03:44:09

US3572251

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

Form: Unblinding

Generated On: 10 Jun 2021 08:20:40

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:52:06
User entered empty.	System	23 Feb 2021 03:44:09

US3572251

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

Form: Unblinding

Generated On: 10 Jun 2021 08:20:40

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:52:06
User entered empty.	System	23 Feb 2021 03:44:09

US3572251

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:52:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:49:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 03:44:28

US3572251

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:52:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:49:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 on 02Feb2021. Please provide accession number and tracking or clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 08:17:52
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 on 02Feb2021. Please provide accession number and tracking or clarify. Thank you.' answered with 'Accession - 1F60113 AWB 939474286270 Shipped 25Feb2021 ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 20:29:48
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the OL-1 on 02Feb2021. Please provide accession number and tracking or clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 20:05:40
User entered '02 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 03:44:28

US3572251

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:52:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:49:21
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '14:22'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 03:44:28

US3572251

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:20:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:52:06
User entered '02 Feb 2021 14:22'	System	23 Feb 2021 03:44:28

US3572251

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:20:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:52:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:49:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 03:44:45

US3572251

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:52:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:49:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '02 Feb 2021'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 03:44:45

US3572251

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:20:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:52:06
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:49:25
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '16:30'	(b) (4) (u) (4), (b) (6)	23 Feb 2021 03:44:45

US3572251

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:20:40

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:52:06
User entered '02 Feb 2021 16:30'	System	23 Feb 2021 03:44:45

US3572251

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:20:40

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User closed query 'Per CDM: AE #5 is recorded as Fatal, however End of Study/Study Discontinuation form is incomplete. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 10:53:14
Query 'Per CDM: AE #5 is recorded as Fatal, however End of Study/Study Discontinuation form is incomplete. Please review and reconcile.' answered with 'PAGE COMPLETED ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 21:43:19
User opened query 'Per CDM: AE #5 is recorded as Fatal, however End of Study/Study Discontinuation form is incomplete. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 13:55:16
User closed query 'Per CDM RQ: Thank you for the response. Please update the field when data is available.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 12:16:01
Query 'Per CDM RQ: Thank you for the response. Please update the field when data is available.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 22:52:55
User opened query 'Per CDM RQ: Thank you for the response. Please update the field when data is available.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 12:32:55
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 201 (27MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 12:32:55
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:01

US3572251

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:20:40

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Safety Follow Up Diary Day 201 (27MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'data to be collected during next safety call ' (Site from DM).	Jackie Ziegler (b) (4)	08 Apr 2021 17:42:08
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 201 (27MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 06:42:35
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	17 Sep 2020 22:28:47

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 14:29:21
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
Un-reviewed for Safety.	(b) (4) (u) (4), (b) (6)	08 Feb 2021 18:30:35
User entered empty; reason for change New Information	(b) (4), (b) (6)	08 Feb 2021 18:30:35
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 14:17:05
User entered 'USA-US091-2021-mRNA-1273-P301000009'	System	03 Feb 2021 14:17:01
User entered 'New'	(b) (4), (b) (6)	03 Feb 2021 14:17:01

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User closed query 'For coding puposes, please clarify FINGER AMPUTATION. Is this a Finger traumatic amputation or Surgical Finger amputation. If surgical, please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' (Site from Coder).	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Site specific injuries NEC, PT: Limb traumatic amputation, LLT: Finger traumatic amputation - version MedDRA\23.0.	(b) (4), (b) (6)	14 Mar 2021 20:49:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	07 Feb 2021 12:59:35
Query 'For coding puposes, please clarify FINGER AMPUTATION. Is this a Finger traumatic amputation or Surgical Finger amputation. If surgical, please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' answered with 'Data updated' (Site from Coder).	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	07 Feb 2021 12:59:35
Coding entries removed.	(b) (4)	
User entered 'Acute traumatic amputation of the index finger at the level of the middle phalanx' reason for change: Data Entry Error	Maria Candelario (b) (4)	06 Feb 2021 00:52:18
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Site specific injuries NEC, PT: Limb injury, LLT: Finger injury - version MedDRA\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Maria Candelario (b) (4)	06 Feb 2021 00:49:15
	(b) (4)	
	System	06 Feb 2021 00:49:29
	Maria Candelario (b) (4)	06 Feb 2021 00:49:15
	(b) (4)	
	Maria Candelario (b) (4)	06 Feb 2021 00:49:15
	(b) (4)	
	Coder Import (b) (4)	03 Feb 2021 17:37:26
	(b) (4)	
	Coder Import (b) (4)	03 Feb 2021 17:37:26
	(b) (4)	

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'For coding puposes, please clarify FINGER AMPUTATION. Is this a Finger traumatic amputation or Surgical Finger amputation. If surgical, please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' (Site from Coder).	(b) (4), (b) (6)	03 Feb 2021 16:23:33
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Finger amputation, LLT: Finger amputation - version MedDRA\\23.0.	Coder Import (b) (4)	03 Feb 2021 02:09:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Feb 2021 02:09:35
Data point term sent to Coder	System	03 Feb 2021 02:08:46
User entered 'Finger amputation'	(b) (4), (b) (6)	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Feb 2021 04:31:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 04:31:04
User entered 'No (N)' reason for change: Data Entry Error	Milton Haber (b) (4)	03 Feb 2021 04:31:04
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Feb 2021 02:08:44
User entered empty.	System	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Feb 2021 04:31:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 04:31:04
User entered 'No (N)' reason for change: Data Entry Error	Milton Haber (b) (4)	03 Feb 2021 04:31:04
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Feb 2021 02:08:44
User entered empty.	System	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered empty.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered empty.	System	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered empty.	System	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	06 Feb 2021 00:52:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Feb 2021 00:52:57
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Maria Candelario (b) (4)	06 Feb 2021 00:52:57
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Feb 2021 02:08:44
User entered empty.	System	03 Feb 2021 02:08:44
	(b) (4), (b) (6)	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User closed query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible.' (Site from Safety).	(b) (4)	
Query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible.' answered with 'Data updated ' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 15:15:20
Query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible.' answered with 'Data updated ' (Site from Safety).	Maria Candelario (b) (4)	06 Feb 2021 00:53:17
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	System	06 Feb 2021 00:49:15
User opened query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible.' (Site from Safety).	Maria Candelario (b) (4)	06 Feb 2021 00:49:15
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' canceled (Site from Safety).	(b) (4)	
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 18:55:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	03 Feb 2021 18:55:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	(b) (4), (b) (6)	03 Feb 2021 18:44:09
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4), (b) (6)	
User entered 'Yes (Y)' reason for change: Data Entry Error	System	03 Feb 2021 04:31:04
	System	03 Feb 2021 04:31:04
	System	03 Feb 2021 04:31:04
	Milton Haber (b) (4)	03 Feb 2021 04:31:04
	(b) (4)	

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 02:08:44
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered '0'	(b) (4) (u) (4), (b) (6)	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered '0'	(b) (4) (u) (4), (b) (6)	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered '0'	(b) (4) (u) (4), (b) (6)	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered '0'	(b) (4) (u) (4), (b) (6)	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Feb 2021 04:31:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 04:31:04
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Milton Haber (b) (4)	03 Feb 2021 04:31:04
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Feb 2021 02:08:44
User entered empty.	System	03 Feb 2021 02:08:44
	(b) (4), (b) (6)	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Feb 2021 04:31:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 04:31:04
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Milton Haber (b) (4)	03 Feb 2021 04:31:04
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Feb 2021 02:08:44
User entered empty.	System	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Feb 2021 04:31:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 04:31:04
User entered 'None (NONE)' reason for change: Data Entry Error	Milton Haber (b) (4)	03 Feb 2021 04:31:04
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Feb 2021 02:08:44
User entered empty.	System	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:12:04
Signature has been broken.	Jessica McDowell (b) (4)	07 Apr 2021 20:57:58
User entered '0' reason for change: Data Entry Error	(b) (4) Jessica McDowell (b) (4)	07 Apr 2021 20:57:58
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	03 Feb 2021 04:31:04
User entered '1' reason for change: Data Entry Error	Milton Haber (b) (4)	03 Feb 2021 04:31:04
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	03 Feb 2021 02:08:44
User entered '0'	(b) (4), (b) (6)	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:12:04
Signature has been broken.	(b) (4)	
	Jessica McDowell (b) (4)	07 Apr 2021 20:57:58
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Jessica McDowell (b) (4)	07 Apr 2021 20:57:58
User signature succeeded.	(b) (4)	
	Milton Haber (u) (4)	22 Mar 2021 03:50:26
User entered '0'	(b) (4)	
	(u) (4), (b) (6)	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered '0'	(b) (4) (u) (4), (b) (6)	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Feb 2021 04:31:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 04:31:04
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Milton Haber (b) (4)	03 Feb 2021 04:31:04
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 02:08:44
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered 'Subject will experience ongoing limitations as a result of finger amputation' reason for change: Data Entry Error	(b) (4) Milton Haber (b) (4)	03 Feb 2021 04:31:04
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4) System	06 Feb 2021 00:49:15
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	06 Feb 2021 00:49:15
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	03 Feb 2021 04:31:04
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '0'	System	06 Feb 2021 00:49:15
User entered '1'	System	03 Feb 2021 04:31:04

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered 'I'	System	03 Feb 2021 02:08:44

US3572251

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:20:40

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User coded data point as SOC: Investigations, HLGT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\23.0.	Coder Import (b) (4)	25 Feb 2021 21:30:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Feb 2021 21:30:00
Data point term sent to Coder	System	25 Feb 2021 21:28:53
User entered 'High Cholesterol'	(b) (4), (b) (6)	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 18:27:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered empty.	System	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered empty.	System	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Mar 2021 18:06:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 18:06:44
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 18:06:44
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 21:28:21
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Mar 2021 18:06:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 18:06:44
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 18:06:44
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 21:28:21
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered '0'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered '0'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered '0'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered '0'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Mar 2021 18:06:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 18:06:44
User entered 'Not Related (NOT RELATED)' reason for change: Per Query Resolution	(b) (4), (b) (6)	05 Mar 2021 18:06:44
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 21:28:21
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Mar 2021 18:06:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 18:06:44
User entered 'Not Related (NOT RELATED)' reason for change: Per Query Resolution	(b) (4), (b) (6)	05 Mar 2021 18:06:44
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 21:28:21
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	05 Mar 2021 18:06:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 18:06:44
User entered 'None (NONE)' reason for change: Per Query Resolution	(b) (4), (b) (6)	05 Mar 2021 18:06:44
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 21:28:21
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered '0'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered 'l'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered '0'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User closed query 'Per CDM: Please update the Outcome of the AE from the list of options available in the eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 03:06:13
Query 'Per CDM: Please update the Outcome of the AE from the list of options available in the eCRF.' answered with 'Data updated' (Site from DM).	Maria Candelario (b) (4)	08 Mar 2021 17:30:49
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Maria Candelario (b) (4)	08 Mar 2021 17:30:36
User opened query 'Per CDM: Please update the Outcome of the AE from the list of options available in the eCRF.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 07:26:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Mar 2021 07:23:44
Query 'Data is required. Please complete.' answered with 'High Cholesterol is not AE' (Site from System).	(b) (4), (b) (6)	05 Mar 2021 18:28:23
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 21:28:21
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:50:26
User entered 'Subject went to the doctor for follow-ups. During this visit the subject got blood work done and it was diagnosed that subject has high cholesterol, medication is recorded in the Con. Med. Log'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '0'	System	05 Mar 2021 18:06:44

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '0'	System	05 Mar 2021 18:27:42
User entered '1'	System	25 Feb 2021 21:28:21

US3572251

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:20:40

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux - version MedDRA\23.0.	Coder Import (b) (4)	31 Mar 2021 17:19:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	31 Mar 2021 17:19:07
Data point term sent to Coder	System	31 Mar 2021 17:17:38
User entered 'Gastric Reflux'	Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '2 Feb 2021'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered empty.	System	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered empty.	System	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Not Related (NOT RELATED)'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Not Related (NOT RELATED)'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'l'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '0'	System	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered 'I'	System	31 Mar 2021 17:16:50

US3572251

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:20:40

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 17:01:12
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:21
User entered 'USA-US091-2021-mRNA-1273-P301000019'	System	15 Apr 2021 14:29:18
User entered 'New'	(b) (4), (b) (6)	15 Apr 2021 14:29:18

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Site specific injuries NEC, PT: Head injury, LLT: Head injury - version MedDRA\23.0.	Coder Import (b) (4)	15 Apr 2021 09:50:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	15 Apr 2021 09:50:50
Data point term sent to Coder	System	14 Apr 2021 19:22:21
User entered 'Head Trauma due to fall'	Maria Candelario (b) (4)	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
User entered 'Yes (Y)'	(b) (4) Maria Candelario (b) (4) (b) (4)	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4) (b) (4)	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4) (b) (4)	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
User entered '3 Apr 2021'	(b) (4) Maria Candelario (b) (4) (b) (4)	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
User entered empty.	(b) (4) Maria Candelario (b) (4) (b) (4)	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered empty.	System	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4) (b) (4)	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
User entered '3 Apr 2021'	(b) (4) Maria Candelario (b) (4) (b) (4)	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
User entered empty.	(b) (4) Maria Candelario (b) (4) (b) (4)	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered empty.	System	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Apr 2021 18:47:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Apr 2021 18:47:43
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Maria Candelario (b) (4)	15 Apr 2021 18:47:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	14 Apr 2021 19:21:39
	Maria Candelario (b) (4)	14 Apr 2021 19:21:39
	(b) (4)	

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
User entered 'Yes (Y)'	(b) (4) Maria Candelario (b) (4) (b) (4)	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
User entered 'l'	(b) (4) Maria Candelario (b) (4) (b) (4)	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User closed query 'Per CDM: Since the subject was not hospitalized, please consider to remove data for ICU admission as it is not required.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 11:30:23
Query 'Per CDM: Since the subject was not hospitalized, please consider to remove data for ICU admission as it is not required.' answered with 'updated per query' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 04:52:53
User opened query 'Per CDM: Since the subject was not hospitalized, please consider to remove data for ICU admission as it is not required.' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 11:08:18
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4), (b) (6)	17 Apr 2021 11:07:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered with 'data updated' (Site from System).	Maria Candelario (b) (4)	15 Apr 2021 19:00:41
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	14 Apr 2021 19:21:39
User entered '0'	Maria Candelario (b) (4)	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
User entered empty.	(b) (4) Maria Candelario (b) (4) (b) (4)	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
User entered empty.	(b) (4) Maria Candelario (b) (4) (b) (4)	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:05:43
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:44
DataPoint Un-verified.	(b) (4) (u) (4), (b) (6)	18 Apr 2021 04:52:28
Signature has been broken.	(b) (4), (b) (6)	18 Apr 2021 04:52:28
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Apr 2021 04:52:28
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4), (b) (6)	17 Apr 2021 11:07:16
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4) (b) (4)	15 Apr 2021 19:16:32
User entered 'No (N)' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	15 Apr 2021 19:03:51
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'Data updated' (Site from System).	Maria Candelario (b) (4) (b) (4)	15 Apr 2021 19:01:49
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	14 Apr 2021 19:21:39
User entered 'Unknown (UNK)'	Maria Candelario (b) (4) (b) (4)	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
User entered empty.	(b) (4) Maria Candelario (b) (4) (b) (4)	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' canceled (Site from Safety).	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(u) (4), (b) (6)	15 Apr 2021 18:47:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Apr 2021 18:47:43
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	15 Apr 2021 18:47:43
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	Maria Candelario (b) (4)	15 Apr 2021 18:47:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 16:19:57
	System	14 Apr 2021 19:21:39
	Maria Candelario (b) (4)	14 Apr 2021 19:21:39
	(b) (4)	

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' canceled (Site from Safety).	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(u) (4), (b) (6)	15 Apr 2021 18:47:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Apr 2021 18:47:43
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	15 Apr 2021 18:47:43
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	Maria Candelario (b) (4)	15 Apr 2021 18:47:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 16:20:10
	System	14 Apr 2021 19:21:39
	Maria Candelario (b) (4)	14 Apr 2021 19:21:39
	(b) (4)	

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Maria Candelario (b) (4) (b) (4)	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
User entered 'l'	(b) (4) Maria Candelario (b) (4) (b) (4)	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
User entered 'Fatal (FATAL)'	(b) (4) Maria Candelario (b) (4) (b) (4)	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
User entered empty.	(b) (4) Maria Candelario (b) (4) (b) (4)	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User signature succeeded.	Milton Haber (b) (4)	30 Apr 2021 16:37:55
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	29 Apr 2021 17:58:05
User closed query 'PV Query: Please provide/confirm the cause of death. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 16:57:01
User closed query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc). Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 16:56:57
User closed query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 16:56:54
Query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so. Please leave query open until information is available.' answered with 'AS PER RECORDS NO AUTOPSY PERFORMED.' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 22:01:32
Query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc). Please leave query open until information is available.' answered with 'UPDATED' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 21:47:21
Query 'PV Query: Please provide/confirm the cause of death. Please leave query open until information is available.' answered with 'UPDATED' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 21:46:51

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT PASSED AWAY ON 03/APR/21. THE SAFETY CALL NURSE CONTACTED SUBJECT FOR E DIARY REMINDER ON 14APR2021 AND THE SUBJECT SISTER ANSWERED THE PHONE; THE SUBJECT HAD FAINTED AND HIT THEIR HEAD; THE SUBJECT WAS TAKEN TO A HOSPITAL (SISTER DOES NOT KNOW THE HOSPITAL NAME SINCE SUBJECT WAS IN ANOTHER COUNTY VISITING THEIR KIDS) WHERE THE SUBJECT DIED OF BLUNT HEAD TRAUMA. SISTER DOES NOT KNOW WHY DID THE SUBJECT FAINTED. SHE STATED THAT THE SUBJECT WAS NOT SICK. THE PI WAS NOTIFIED IMMEDIATELY AND THE CRA VIA EMAIL, IRB, EPIF AND EDC SUBMITTED 14APR2021. WILL ATTEMPT TO REQUEST ADDITIONAL INFORMATION IN ORDER TO REQUEST MEDICAL RECORDS. THE SUBJECT PRESENTS TO ER FOLLOWING FALL. THE ONSET WAS JUST PRIOR TO ARRIVAL. THE OCCURRENCE WAS SINGLE EPISODE. THE FALL WAS DESCRIBED AS FELL DOWN 10 STEPS. THE LOCATION WHERE THE INCIDENT OCCURED WAS AT HOME. LOCATION: RIGHT SCALP. THE CHARACTER OF SYPMTOMS IS SWELLING AND BLEEDING. THE DEGREE IS PRESENT IS SEVERE. CAUSE OF DEATH: HEAD TRAUMA ALCHOL INTOXICATION,ACCIDENTAL FALL DOWN STAIRS, CARDIOPULMONARY ARREST' reason for change: Data Entry Error DataPoint Un-verified.	(b) (4), (b) (6)	28 Apr 2021 21:46:21
	(b) (4), (b) (6)	28 Apr 2021 21:41:24
Signature has been broken.	(b) (4), (b) (6)	28 Apr 2021 21:41:24

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT PASSED AWAY ON 03/APR/21. THE SAFETY CALL NURSE CONTACTED SUBJECT FOR E DIARY REMINDER ON 14APR2021 AND THE SUBJECT SISTER ANSWERED THE PHONE; THE SUBJECT HAD FAINTED AND HIT THEIR HEAD; THE SUBJECT WAS TAKEN TO A HOSPITAL (SISTER DOES NOT KNOW THE HOSPITAL NAME SINCE SUBJECT WAS IN ANOTHER COUNTY VISITING THEIR KIDS) WHERE THE SUBJECT DIED OF BLUNT HEAD TRAUMA. SISTER DOES NOT KNOW WHY DID THE SUBJECT FAINTED. SHE STATED THAT THE SUBJECT WAS NOT SICK. THE PI WAS NOTIFIED IMMEDIATELY AND THE CRA VIA EMAIL, IRB, EPIF AND EDC SUBMITTED 14APR2021. WILL ATTEMPT TO REQUEST ADDITIONAL INFORMATION IN ORDER TO REQUEST MEDICAL RECORDS. THE SUBJECT PRESENTS TO ER FOLLOWING FALL. THE ONSET WAS JUST PRIOR TO ARRIVAL. THE OCCURRENCE WAS SINGLE EPISODE. THE FALL WAS DESCRIBED AS FELL DOWN 10 STEPS. THE LOCATION WHERE THE INCIDENT OCCURED WAS AT HOME. LOCATION: RIGHT SCALP. THE CHARACTER OF SYPMTOMS IS SWELLING AND BLEEDING. THE DEGREE IS PRESENT IS SEVERE. ALCHOL INTOXICATION,ACCIDENTAL FALL DOWN STAIRS.' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Apr 2021 21:41:24
User opened query 'PV Query: Please provide/confirm the cause of death. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 13:33:07
User opened query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc). Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 13:31:59

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 13:31:18
User closed query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 11:53:43
User closed query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 11:53:40
User closed query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc)' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 11:53:36
Query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so.' answered with 'Pending Medical Records' (Site from Safety).	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 03:07:36
Query 'PV Query: Please provide/confirm the cause of death.' answered with 'Pending Medical Records' (Site from Safety).	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 03:07:18
Query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc)' answered with 'Pending Medical Records' (Site from Safety).	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 03:07:00
User opened query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:11:36
User opened query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:11:24
User opened query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc)' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:11:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:57:06

PRODUCTION RELEASE (v12.003
EAB) (1725)

1809 of 2127

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
User entered 'Subject passed away on 03/Apr/21. The safety call nurse contacted subject for e Diary reminder on 14Apr2021 and the subject sister answered the phone; the Subject had fainted and hit their head; the subject was taken to a hospital (sister does not know the hospital name since subject was in another county visiting their kids) where the subject died of Blunt Head Trauma. Sister does not know why did the subject fainted. She stated that the subject was not sick. The PI was notified immediately and the CRA via email, IRB, epif and edc submitted 14Apr2021. Will attempt to request additional information in order to request medical records.'	Maria Candelario (b) (4)	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered 'I'	System	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered 'I'	System	14 Apr 2021 19:21:39

US3572251

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:20:40

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '0'	System	14 Apr 2021 19:21:39

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User closed query 'Per source, please spell out indication for con meds noted.' (Site from CRA).	(b) (4)	
Query 'Per source, please spell out indication for con meds noted.' answered with 'indications reconciled with complete spelling' (Site from CRA).	(b) (4), (b) (6)	15 Jan 2021 04:23:37
User opened query 'Per source, please spell out indication for con meds noted.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 19:58:43
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:47:24
	(b) (4), (b) (6)	28 Sep 2020 21:16:04
User entered 'Yes (Y)'	Jackie Ziegler (b) (4)	24 Sep 2020 14:16:29
	(b) (4)	

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS, PRODUCT: EMPAGLIFLOZIN;LINAGLIPTIN, PRODUCTSYNONYM: GLYXAMBI - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 19:58:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 19:58:31
Data point term sent to Coder	System	05 Jan 2021 19:57:34
Coding entries removed.	(b) (4), (b) (6)	05 Jan 2021 19:57:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS, PRODUCT: EMPAGLIFLOZIN;LINAGLIPTIN, PRODUCTSYNONYM: GLYXAMBI - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 14:18:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 14:18:58
Data point term sent to Coder	System	24 Sep 2020 14:17:30
User entered 'Glyxambi'	Jackie Ziegler (b) (4)	24 Sep 2020 14:17:03

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)'	Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:17:03

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Diabetes Mellitus Type 2' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 19:57:00
User entered 'DMII'	Jackie Ziegler (b) (4)	24 Sep 2020 14:17:03
	(b) (4)	

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered '25/5'	Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:17:03

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'mg (mg)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:17:03

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:17:03

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'once daily (QD)'	Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:17:03

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:17:03

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'Oral (ORAL)'	Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:17:03

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:40

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered empty.	Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:17:03

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '15 Jul 2020'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:17:03

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:17:03

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:17:03

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:17:03

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:17:03

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered 'I'	System	24 Sep 2020 14:17:03

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered 'I'	System	24 Sep 2020 14:17:03

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:20:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '804 (804)'	System	24 Sep 2020 14:17:03

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:40

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: NOVOLOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 19:58:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 19:58:30
Data point term sent to Coder	System	05 Jan 2021 19:57:34
Coding entries removed.	(b) (4), (b) (6)	05 Jan 2021 19:57:33
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: NOVOLOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 11:37:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 11:37:51
Data point term sent to Coder	System	24 Sep 2020 14:19:40
User entered 'Novolog'	Jackie Ziegler (b) (4)	24 Sep 2020 14:18:46

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)'	Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:18:46

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Diabetes Mellitus Type 2' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 19:57:33
User entered 'DMII'	Jackie Ziegler (b) (4)	24 Sep 2020 14:18:46
	(b) (4)	

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '14/7'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:18:46

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'IU (IU)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:18:46

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:18:46

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'other (OTHER)'	Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:18:46

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered '14 iu before breakfast, 7 iu before dinner'	Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:18:46

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:18:46

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:18:46

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '01 Jul 2020'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:18:46

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:18:46

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:18:46

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:18:46

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)'	Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:18:46

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered empty.	System	24 Sep 2020 14:18:46

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered empty.	System	24 Sep 2020 14:18:46

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:20:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered empty.	System	24 Sep 2020 14:18:46

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 19:59:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 19:59:30
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	05 Jan 2021 19:58:34 05 Jan 2021 19:57:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 14:21:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 14:21:26
Data point term sent to Coder User entered 'lisinopril'	System Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:19:41 24 Sep 2020 14:19:35

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)'	Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:19:35

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Hypertension' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 19:57:53
User entered 'HTN'	Jackie Ziegler (b) (4)	24 Sep 2020 14:19:35
	(b) (4)	

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '20'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:19:35

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'mg (mg)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:19:35

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:19:35

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'once daily (QD)'	Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:19:35

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered empty.	Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:19:35

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Oral (ORAL)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:19:35

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:19:35

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '01 Jul 2008'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:19:35

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '0'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:19:35

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:19:35

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:19:35

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)'	Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:19:35

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered 'I'	System	24 Sep 2020 14:19:35

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered 'I'	System	24 Sep 2020 14:19:35

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:20:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '804 (804)'	System	24 Sep 2020 14:19:35

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 21:23:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 21:23:00
Data point term sent to Coder	System	25 Feb 2021 21:07:27
Coding entries removed.	(b) (4), (b) (6)	25 Feb 2021 21:06:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Dec 2020 17:01:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Dec 2020 17:01:47
Data point term sent to Coder	System	02 Dec 2020 17:01:11
User entered 'tylenol'	Jessica McDowell (b) (4)	02 Dec 2020 17:00:33

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)'	Jessica McDowell (b) (4) (b) (4)	02 Dec 2020 17:00:33

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User closed query 'Per DM CLR: Please review AE eCRF's AE #2 ACUTE TRAUMATIC AMPUTATION OF THE INDEX FINGER AT THE LEVEL OF THE MIDDLE PHALANX (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 09:43:52
Query 'Per DM CLR: Please review AE eCRF's AE #2 ACUTE TRAUMATIC AMPUTATION OF THE INDEX FINGER AT THE LEVEL OF THE MIDDLE PHALANX (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' answered with 'updated' (Site from DM).	Jessica McDowell (b) (4)	07 Apr 2021 20:58:16
User opened query 'Per DM CLR: Please review AE eCRF's AE #2 ACUTE TRAUMATIC AMPUTATION OF THE INDEX FINGER AT THE LEVEL OF THE MIDDLE PHALANX (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 04:37:49
User closed query 'Per DM CLR RQ: Kindly note that start date of ConMed (10 NOV 2020) is prior to the start date of the indicated AE (11 NOV 2020). Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 02:51:48
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Query 'Per DM CLR RQ: Kindly note that start date of ConMed (10 NOV 2020) is prior to the start date of the indicated AE (11 NOV 2020). Please review and reconcile.' answered with 'Per source medication started on 10NOV2020' (Site from DM).	Carlin roll (b) (4)	26 Mar 2021 14:56:36

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:40

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR RQ: Kindly note that start date of ConMed (10 NOV 2020) is prior to the start date of the indicated AE (11 NOV 2020). Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 07:34:04
User closed query 'Per DM CLR RQ: Please note that timeframe of the ConMed does not match with the corresponding AE recorded in AE eCRF. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 07:34:04
Query 'Per DM CLR RQ: Please note that timeframe of the ConMed does not match with the corresponding AE recorded in AE eCRF. Please review and reconcile.' answered with 'dates updated ' (Site from DM).	Jasmine Ali (b) (4) (b) (4)	23 Mar 2021 15:48:14
User opened query 'Per DM CLR RQ: Please note that timeframe of the ConMed does not match with the corresponding AE recorded in AE eCRF. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 10:40:37
User closed query 'Per DM CLR: Please update indication to ensure that the location of PAIN is specified, and ensure that a corresponding Adverse event/ Medical History condition is recorded, since there is no corresponding AE or MH recorded. Update as appropriate or provide clarification ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 10:40:37
User entered 'PAIN for finger amputation' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 21:06:34
Query 'Per DM CLR: Please update indication to ensure that the location of PAIN is specified, and ensure that a corresponding Adverse event/ Medical History condition is recorded, since there is no corresponding AE or MH recorded. Update as appropriate or provide clarification ' answered with 'Generalized' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 20:13:52
User opened query 'Per DM CLR: Please update indication to ensure that the location of PAIN is specified, and ensure that a corresponding Adverse event/ Medical History condition is recorded, since there is no corresponding AE or MH recorded. Update as appropriate or provide clarification ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 09:17:50
User entered 'pain'	Jessica McDowell (b) (4) (b) (4)	02 Dec 2020 17:00:33

PRODUCTION RELEASE (v12.003
EAB) (1725)

1872 of 2127

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '500'	(b) (4) Jessica McDowell (b) (4) (b) (4)	02 Dec 2020 17:00:33

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'mg (mg)'	Jessica McDowell (b) (4) (b) (4)	02 Dec 2020 17:00:33

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered empty.	Jessica McDowell (b) (4) (b) (4)	02 Dec 2020 17:00:33

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'three times daily (TID)'	Jessica McDowell (b) (4) (b) (4)	02 Dec 2020 17:00:33

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered empty.	Jessica McDowell (b) (4) (b) (4)	02 Dec 2020 17:00:33

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'Oral (ORAL)'	Jessica Mcdowell (b) (4) (b) (4)	02 Dec 2020 17:00:33

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:40

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered empty.	Jessica McDowell (b) (4) (b) (4)	02 Dec 2020 17:00:33

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered '10 Nov 2020' reason for change: Per Query Resolution	Jasmine Ali (b) (4) (b) (4)	23 Mar 2021 15:44:38
User entered '10 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 21:06:34
User entered '10 Nov 2020'	Jessica McDowell (b) (4) (b) (4)	02 Dec 2020 17:00:33

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered '0'	Jessica McDowell (b) (4) (b) (4)	02 Dec 2020 17:00:33

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	(u) (4), (b) (6)	25 Feb 2021 21:06:34
User entered 'Yes (Y)'	Jessica Mcdowell (b) (4)	02 Dec 2020 17:00:33
	(b) (4)	

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered '30 Nov 2020' reason for change: New Information	Jasmine Ali (b) (4) (b) (4)	23 Mar 2021 15:44:38
User entered '10 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 21:06:34
User entered empty.	Jessica McDowell (b) (4) (b) (4)	02 Dec 2020 17:00:33

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)'	Jessica McDowell (b) (4) (b) (4)	02 Dec 2020 17:00:33

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:39
User entered '3'	System	02 Dec 2020 17:00:33

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:39
User entered 'I'	System	02 Dec 2020 17:00:33

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:20:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:39
User entered '804 (804)'	System	02 Dec 2020 17:00:33

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 07:57:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 07:57:10
Data point term sent to Coder	System	25 Feb 2021 21:07:25
Coding entries removed.	(b) (4), (b) (6)	25 Feb 2021 21:06:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Dec 2020 17:02:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Dec 2020 17:02:48
Data point term sent to Coder	System	02 Dec 2020 17:02:13
User entered 'gabapentin'	Jessica McDowell (b) (4)	02 Dec 2020 17:01:16

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)'	Jessica Mcdowell (b) (4) (b) (4)	02 Dec 2020 17:01:16

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User closed query 'Per DM CLR: Please update indication to ensure that the location of PAIN is specified, and ensure that a corresponding Adverse event/ Medical History condition is recorded, since there is no corresponding AE or MH recorded. Update as appropriate or provide clarification ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 05:42:28
Query 'Per DM CLR: Please update indication to ensure that the location of PAIN is specified, and ensure that a corresponding Adverse event/ Medical History condition is recorded, since there is no corresponding AE or MH recorded. Update as appropriate or provide clarification ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 21:06:49
User entered 'PAIN in amputated finger' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 21:06:43
User opened query 'Per DM CLR: Please update indication to ensure that the location of PAIN is specified, and ensure that a corresponding Adverse event/ Medical History condition is recorded, since there is no corresponding AE or MH recorded. Update as appropriate or provide clarification ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 09:18:13
User entered 'pain'	Jessica McDowell (b) (4) (b) (4)	02 Dec 2020 17:01:16

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '300'	(b) (4) Jessica McDowell (b) (4) (b) (4)	02 Dec 2020 17:01:16

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'mg (mg)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	02 Dec 2020 17:01:16

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered empty.	Jessica McDowell (b) (4) (b) (4)	02 Dec 2020 17:01:16

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered 'three times daily (TID)'	Jessica McDowell (b) (4) (b) (4)	02 Dec 2020 17:01:16

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered empty.	Jessica McDowell (b) (4) (b) (4)	02 Dec 2020 17:01:16

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Oral (ORAL)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	02 Dec 2020 17:01:16

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:40

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
User entered empty.	Jessica McDowell (b) (4) (b) (4)	02 Dec 2020 17:01:16

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:12:04
User closed query 'Per DM CLR RQ: Response noted. However the Conmed Start date is updated as 10 Oct2020 which is prior to the start date of the corresponding AE(11Nov2020).Please review and reconcile the Con Med and AE start dates if applicable. ' (Site from DM).	(b) (4)	
Query 'Per DM CLR RQ: Response noted. However the Conmed Start date is updated as 10 Oct2020 which is prior to the start date of the corresponding AE(11Nov2020).Please review and reconcile the Con Med and AE start dates if applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 09:45:27
Signature has been broken.	Jessica McDowell (b) (4)	07 Apr 2021 20:59:00
	(b) (4)	
User entered '11 Nov 2020' reason for change: Data Entry Error	Jessica McDowell (b) (4)	07 Apr 2021 20:58:54
User opened query 'Per DM CLR RQ: Response noted. However the Conmed Start date is updated as 10 Oct2020 which is prior to the start date of the corresponding AE(11Nov2020).Please review and reconcile the Con Med and AE start dates if applicable. ' (Site from DM).	Jessica McDowell (b) (4)	07 Apr 2021 20:58:54
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 02:52:12
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. ' answered with 'Per source, the medication started on 10NOV2020.' (Site from DM).	(b) (4)	
	Carlin roll (b) (4)	26 Mar 2021 15:00:49

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 02:54:16
User entered '10 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 21:06:43
User entered '10 Nov 2020'	Jessica McDowell (b) (4) (b) (4)	02 Dec 2020 17:01:16

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '0'	(b) (4) Jessica McDowell (b) (4) (b) (4)	02 Dec 2020 17:01:16

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	(u) (4), (b) (6)	25 Feb 2021 21:06:43
User entered 'Yes (Y)'	Jessica McDowell (b) (4)	02 Dec 2020 17:01:16
	(b) (4)	

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:12:04
User closed query 'End date is prior to start date. Please correct.' (Site from System).	(b) (4)	
Signature has been broken.	System	07 Apr 2021 20:59:09
	Jessica McDowell (b) (4)	07 Apr 2021 20:59:09
User entered '24 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Jessica McDowell (b) (4)	07 Apr 2021 20:59:09
User opened query 'End date is prior to start date. Please correct.' (Site from System).	(b) (4)	
User signature succeeded.	System	07 Apr 2021 20:58:54
	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '24 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	(u) (4), (b) (6)	25 Feb 2021 21:06:43
User entered empty.	Jessica McDowell (b) (4)	02 Dec 2020 17:01:16
	(b) (4)	

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:41
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	02 Dec 2020 17:01:16

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:41
User entered '3'	System	02 Dec 2020 17:01:16

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:41
User entered 'I'	System	02 Dec 2020 17:01:16

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:20:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:29:41
User entered '804 (804)'	System	02 Dec 2020 17:01:16

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: LANSOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 21:11:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 21:11:00
Data point term sent to Coder	System	25 Feb 2021 21:10:29
User entered 'Lansoprazole'	(b) (4), (b) (6)	25 Feb 2021 21:09:51

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:09:51

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 01:59:36
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:57:18
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'AE for Gastric Reflux added' (Site from DM).	Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:19:43
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 02:55:05
User entered 'Reflux'	(b) (4), (b) (6)	25 Feb 2021 21:09:51

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '30'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 21:09:51

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:09:51

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:09:51

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:09:51

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) (u) (4), (b) (6)	25 Feb 2021 21:09:51

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:09:51

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:40

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) (u) (4), (b) (6)	25 Feb 2021 21:09:51

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:09:51

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '0'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 21:09:51

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 21:09:51

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:09:51

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) . Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 02:55:45
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) . Please review and update as appropriate. Otherwise, provide clarification.' answered with 'Medication was not for solicited event, response changed to NO.' (Site from DM).	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 17:20:22
User entered 'No (N)' reason for change: Per Query Resolution	Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:57:51
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) . Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 02:54:56

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 21:09:51

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered 'I'	System	25 Feb 2021 21:09:51

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered 'I'	System	25 Feb 2021 21:09:51

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:20:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '804 (804)'	System	25 Feb 2021 21:09:51

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:40

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: CANDESARTAN CILEXETIL, PRODUCTSYNONYM: ATACAND - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 21:29:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 21:29:06
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: CANDESARTAN CILEXETIL, PRODUCTSYNONYM: ATACAND - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 21:13:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 21:13:07
Data point term sent to Coder	System	25 Feb 2021 21:12:33
User entered 'Atacand'	(b) (4), (b) (6)	25 Feb 2021 21:12:28

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:12:28

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Hypertension'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:12:28

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 10:29:33
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' ' answered with 'UPDATED' (Site from DM).	Caitlin roll (b) (4)	26 Mar 2021 15:05:51
User entered '16/12.5' reason for change: Data Entry Error	Caitlin roll (b) (4)	26 Mar 2021 15:05:47
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 02:51:49
User entered '12.5'	(b) (4), (b) (6)	25 Feb 2021 21:12:28

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:12:28

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:12:28

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:12:28

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:12:28

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:12:28

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:12:28

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:12:28

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '0'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 21:12:28

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 21:12:28

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:12:28

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:12:28

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered 'I'	System	25 Feb 2021 21:12:28

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered 'I'	System	25 Feb 2021 21:12:28

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:20:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '804 (804)'	System	25 Feb 2021 21:12:28

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Feb 2021 21:15:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 21:15:01
Data point term sent to Coder	System	25 Feb 2021 21:14:35
User entered 'Lipitor'	(b) (4), (b) (6)	25 Feb 2021 21:14:15

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:14:15

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'High Cholesterol'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:14:15

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '10'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 21:14:15

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:14:15

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:14:15

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:14:15

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:14:15

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:14:15

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:40

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) (u) (4), (b) (6)	25 Feb 2021 21:14:15

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:14:15

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '0'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 21:14:15

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	25 Feb 2021 21:14:15

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:14:15

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:14:15

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered 'I'	System	25 Feb 2021 21:14:15

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered 'I'	System	25 Feb 2021 21:14:15

US3572251

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:20:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '804 (804)'	System	25 Feb 2021 21:14:15

US3572251

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:20:40

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:45:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	24 Sep 2020 14:19:45

US3572251

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:20:40

[Date of study discontinuation/completion \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:26:49
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:59
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	26 Apr 2021 18:27:21
User entered '3 Apr 2021'	(b) (4), (b) (6)	23 Apr 2021 21:42:45

US3572251

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:20:40

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:26:49
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:59
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	26 Apr 2021 18:27:21
User entered 'Death (DEATH)'	(b) (4), (b) (6)	23 Apr 2021 21:42:45

US3572251

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:20:40

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)	29 Apr 2021 06:26:49
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:59
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	26 Apr 2021 18:27:21
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 21:42:45

US3572251

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:20:40

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:26:49
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:59
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	26 Apr 2021 18:27:21
User closed query 'Reason for discontinuation is Death, however main cause of death is missing. Please provide.' (Site from System).	System	23 Apr 2021 21:43:08
User entered 'Adverse event (ADVERSE EVENT)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 21:43:08
User opened query 'Reason for discontinuation is Death, however main cause of death is missing. Please provide.' (Site from System).	System	23 Apr 2021 21:42:45
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 21:42:45

US3572251

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:20:40

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:26:49
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:59
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	26 Apr 2021 18:27:21
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 21:42:45

US3572251

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:20:40

Date of death (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:26:49
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:59
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	26 Apr 2021 18:27:21
User closed query 'Reason for discontinuation is Death, however date of death is missing. Please provide.' (Site from System).	System	23 Apr 2021 21:43:08
User entered '3 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 21:43:08
User opened query 'Reason for discontinuation is Death, however date of death is missing. Please provide.' (Site from System).	System	23 Apr 2021 21:42:45
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 21:42:45

US3572251

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:20:40

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:26:49
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:11:59
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	26 Apr 2021 18:27:21
User closed query 'Reason for discontinuation is Death, however response to was autopsy performed is missing. Please provide.' (Site from System).	System	23 Apr 2021 21:43:08
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 21:43:08
User opened query 'Reason for discontinuation is Death, however response to was autopsy performed is missing. Please provide.' (Site from System).	System	23 Apr 2021 21:42:45
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 21:42:45

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'USA-US091-2021-MRNA-1273-P301000009'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'No (N)'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'No (N)'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'No (N)'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'No (N)'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'No (N)'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'No (N)'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'No (N)'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'Milton'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'Haber'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered '2344 Laguna Del Mar, Suite 201'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'Laredo'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'TX'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered '78041'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:15:30
User entered 'US'	System	03 Feb 2021 16:02:57

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '3'	System	08 Feb 2021 15:29:16
User entered '2'	System	08 Feb 2021 15:15:41
User entered '1'	System	03 Feb 2021 16:02:57

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'USA-US091-2021-MRNA-1273-P301000009'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'No (N)'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'No (N)'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'No (N)'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'No (N)'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'No (N)'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'No (N)'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'No (N)'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'Milton'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'Haber'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered '2344 Laguna Del Mar, Suite 201'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'Laredo'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'TX'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered '78041'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:15:30
User entered 'US'	System	03 Feb 2021 16:02:57

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '3'	System	08 Feb 2021 15:29:16
User entered '2'	System	08 Feb 2021 15:15:41
User entered '1'	System	03 Feb 2021 16:02:57

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:20:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '03/Feb/2021 16:02'	(b) (4) System	03 Feb 2021 16:02:57

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:20:40

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)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:15:30
User entered 'I'	(b) (4), (b) (6)	03 Feb 2021 16:02:57

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'USA-US091-2021-MRNA-1273-P301000009'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'No (N)'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'No (N)'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'No (N)'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'No (N)'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'No (N)'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'No (N)'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'No (N)'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'Milton'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'Haber'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered '2344 Laguna Del Mar, Suite 201'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'Laredo'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'TX'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered '78041'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:15:30
User entered 'US'	System	03 Feb 2021 16:02:57

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '3'	System	08 Feb 2021 15:29:16
User entered '2'	System	08 Feb 2021 15:15:41
User entered '1'	System	03 Feb 2021 16:02:57

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:20:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '08/Feb/2021 15:15'	(b) (4) System	08 Feb 2021 15:15:41

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:20:40

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)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:29:04
User entered 'I'	(b) (4), (b) (6)	08 Feb 2021 15:15:41

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'USA-US091-2021-MRNA-1273-P301000009'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'No (N)'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'No (N)'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'No (N)'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'No (N)'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'No (N)'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'No (N)'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'No (N)'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'Milton'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'Haber'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered '2344 Laguna Del Mar, Suite 201'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'Laredo'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered 'TX'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:02:42
User entered '78041'	System	03 Feb 2021 14:17:01

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:15:30
User entered 'US'	System	03 Feb 2021 16:02:57

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '3'	System	08 Feb 2021 15:29:16
User entered '2'	System	08 Feb 2021 15:15:41
User entered '1'	System	03 Feb 2021 16:02:57

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:20:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered '08/Feb/2021 15:29'	(b) (4) System	08 Feb 2021 15:29:16

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:20:40

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)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:43:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:57:18
User entered 'l'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:29:16

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'USA-US091-2021-MRNA-1273-P301000019'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'Yes (Y)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'Yes (Y)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'No (N)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'No (N)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'No (N)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'No (N)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'No (N)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'Milton'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'Haber'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered '2344 Laguna Del Mar, Suite 201'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'Laredo'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'TX'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered '78041'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 18:48:07
User entered 'US'	System	15 Apr 2021 14:29:47

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '4'	System	29 Apr 2021 17:02:05
User entered '3'	System	19 Apr 2021 12:59:20
User entered '2'	System	15 Apr 2021 18:48:15
User entered '1'	System	15 Apr 2021 14:29:47

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'USA-US091-2021-MRNA-1273-P301000019'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'Yes (Y)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'Yes (Y)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'No (N)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'No (N)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'No (N)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'No (N)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'No (N)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'Milton'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'Haber'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered '2344 Laguna Del Mar, Suite 201'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'Laredo'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'TX'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered '78041'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 18:48:07
User entered 'US'	System	15 Apr 2021 14:29:47

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '4'	System	29 Apr 2021 17:02:05
User entered '3'	System	19 Apr 2021 12:59:20
User entered '2'	System	15 Apr 2021 18:48:15
User entered '1'	System	15 Apr 2021 14:29:47

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:20:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
User entered '15/Apr/2021 10:29'	(b) (4) System	15 Apr 2021 14:29:47

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:20:40

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)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 18:48:07
User entered 'I'	(b) (4), (b) (6)	15 Apr 2021 14:29:47

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'USA-US091-2021-MRNA-1273-P301000019'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'Yes (Y)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'Yes (Y)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'No (N)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'No (N)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'No (N)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'No (N)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'No (N)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'Milton'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'Haber'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered '2344 Laguna Del Mar, Suite 201'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'Laredo'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'TX'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered '78041'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 18:48:07
User entered 'US'	System	15 Apr 2021 14:29:47

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '4'	System	29 Apr 2021 17:02:05
User entered '3'	System	19 Apr 2021 12:59:20
User entered '2'	System	15 Apr 2021 18:48:15
User entered '1'	System	15 Apr 2021 14:29:47

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:20:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
User entered '15/Apr/2021 14:48'	(b) (4) System	15 Apr 2021 18:48:15

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:20:40

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)	02 May 2021 17:19:39
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:58:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
User entered 'I'	(b) (4) (u) (4), (b) (6)	15 Apr 2021 18:48:15

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'USA-US091-2021-MRNA-1273-P301000019'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'Yes (Y)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'Yes (Y)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'No (N)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'No (N)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'No (N)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'No (N)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'No (N)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'Milton'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'Haber'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered '2344 Laguna Del Mar, Suite 201'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'Laredo'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'TX'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered '78041'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 18:48:07
User entered 'US'	System	15 Apr 2021 14:29:47

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '4'	System	29 Apr 2021 17:02:05
User entered '3'	System	19 Apr 2021 12:59:20
User entered '2'	System	15 Apr 2021 18:48:15
User entered '1'	System	15 Apr 2021 14:29:47

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:20:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User signature succeeded.	Milton Haber (b) (4)	20 Apr 2021 05:41:14
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	19 Apr 2021 17:05:27
User entered '19/Apr/2021 08:59'	System	19 Apr 2021 12:59:20

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:20:40

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)	02 May 2021 17:19:39
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 17:01:42
User signature succeeded.	Milton Haber (b) (4)	20 Apr 2021 05:41:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:05:27
User entered 'I'	(b) (4), (b) (6)	19 Apr 2021 12:59:20

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'USA-US091-2021-MRNA-1273-P301000019'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'Yes (Y)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'Yes (Y)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'No (N)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'No (N)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'No (N)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'No (N)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'No (N)'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'Milton'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'Haber'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered '2344 Laguna Del Mar, Suite 201'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'Laredo'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered 'TX'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 14:29:39
User entered '78041'	System	15 Apr 2021 14:29:18

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:28
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:16:32
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 18:48:07
User entered 'US'	System	15 Apr 2021 14:29:47

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 10 Jun 2021 08:20:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User entered '4'	System	29 Apr 2021 17:02:05
User entered '3'	System	19 Apr 2021 12:59:20
User entered '2'	System	15 Apr 2021 18:48:15
User entered '1'	System	15 Apr 2021 14:29:47

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:20:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:39
User signature succeeded.	Milton Haber (b) (4)	30 Apr 2021 16:37:55
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	30 Apr 2021 14:39:55
User entered '29/Apr/2021 13:02'	System	29 Apr 2021 17:02:05

US3572251

Folder: SAE USA-US091-2021-MRNA-1273-P301000019

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:20:40

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)	02 May 2021 17:19:39
User signature succeeded.	Milton Haber (b) (4)	30 Apr 2021 16:37:55
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	30 Apr 2021 14:39:55
User entered 'l'	(b) (4), (b) (6)	29 Apr 2021 17:02:05