

US3572086 (Prod: Laguna Clinical Research Associates)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:18:18

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US3572086

Form: Participant Creation

Data signed: (b) (4) 03 Apr 2021 04:25:33

Generated On: 10 Jun 2021 08:18:18

[Participant ID](#)

US3572086

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

US3572086

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 20 Mar 2021 23:49:17

Generated On: 10 Jun 2021 08:18:18

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	25 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 20 Mar 2021 23:49:17

Generated On: 10 Jun 2021 08:18:18

Date of Birth (MMM yyyy)	(b) (6) 1956
Age	63
Age Units	YEARS
Age (Derived)	63
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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 20 Mar 2021 23:49:17

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Date of Informed Consent (<i>dd MMM yyyy</i>)	25 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐ Amendment 2 ☐ Amendment 3 ☒ Amendment 4 ☐ Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒ No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐ Inclusion/Exclusion ☐ Cohort Full ☐ Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐ No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 20 Mar 2021 23:49:17

Generated On: 10 Jun 2021 08:18:18

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 20 Mar 2021 23:49:17

Generated On: 10 Jun 2021 08:18:18

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 20 Mar 2021 23:49:17

Generated On: 10 Jun 2021 08:18:18

Condition	CEREBROVASCULAR-ACCIDENT (CVA)
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 20 Mar 2021 23:49:17

Generated On: 10 Jun 2021 08:18:18

Condition	CEREBROVASCULAR-ACCIDENT (CVA)
Start date (dd MMM yyyy)	UN FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN FEB 2020
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	FEB 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 20 Mar 2021 23:49:17

Generated On: 10 Jun 2021 08:18:18

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 20 Mar 2021 23:49:17

Generated On: 10 Jun 2021 08:18:18

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 20 Mar 2021 23:49:17

Generated On: 10 Jun 2021 08:18:18

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	25 AUG 2020
Time of assessment (00:00-23:59)	10:54 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 10:54
Height (xxx.x)	65 in
Weight (xxx.x)	189 lb
BMI (xxx.x)	31.51701 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 20 Mar 2021 23:49:17

Generated On: 10 Jun 2021 08:18:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Mar 2021 23:49:17

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

DISABLED/ RETIRED

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Mar 2021 23:49:17

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	25 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

What was the date of randomization? (dd MMM yyyy) 25 AUG 2020

What was the participant's randomization number? 144837

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☐
 >=18 and <65 years and at risk ☒
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☒ No ☐

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

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)	25 AUG 2020
Time of assessment (00:00-23:59)	10:54 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 10:54
Temperature (xxx.x)	98.1 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	157 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

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)	25 AUG 2020
Time of assessment (00:00-23:59)	11:40 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 11:40
Temperature (xxx.x)	98.1 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

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) 25 AUG 2020

What was the treatment time? (00:00-23:59) 11:10 (24 HR)

Treatment Date and Time (derived) 25 AUG 2020 11:10

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	25 AUG 2020
Collection time (00:00-23:59)	10:55 (24 HR)
Collection date and time (derived)	25 AUG 2020 10:55

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

Collection date (dd MMM yyyy)			25 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:03	25 AUG 2020 11:03
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 11:56

PC Open Date & Time

25 AUG 2020 11:30

PC Close Date & Time

25 AUG 2020 14:00

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	25 AUG 2020 18:03
PC Open Date & Time	25 AUG 2020 14:55
PC Close Date & Time	26 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:18

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 18:43

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:18

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 18:50

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 18:46

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 18:54

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 19:37

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 18:19

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

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

25 AUG 2020 11:56

PC Open Date & Time

25 AUG 2020 11:30

PC Close Date & Time

25 AUG 2020 14:00

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

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

25 AUG 2020 18:03

PC Open Date & Time

25 AUG 2020 14:55

PC Close Date & Time

26 AUG 2020 11:59

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:18

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

26 AUG 2020 18:43

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:18

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

27 AUG 2020 18:51

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:18

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	28 AUG 2020 18:45
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:18

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

29 AUG 2020 18:54

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:18

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

30 AUG 2020 19:35

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:18

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

31 AUG 2020 18:18

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

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 ☐

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 11:56
PC Open Date & Time	25 AUG 2020 11:30
PC Close Date & Time	25 AUG 2020 14:00

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

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 ☐

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 18:04
PC Open Date & Time	25 AUG 2020 14:55
PC Close Date & Time	26 AUG 2020 11:59

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:18

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 ☒

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:18

Yes ☐	
PC Time stamp	26 AUG 2020 18:44
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:18

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 ☒

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EAB) (1725)

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:18

Yes ☐	
PC Time stamp	27 AUG 2020 18:51
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:18

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

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EAB) (1725)

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:18

Yes ☐	
PC Time stamp	28 AUG 2020 18:47
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:18

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

51 of 2167

EAB) (1725)

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:18

Yes ☐	
PC Time stamp	29 AUG 2020 18:54
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:18

Yes ☐	
PC Time stamp	30 AUG 2020 19:36
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:18

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

55 of 2167

EAB) (1725)

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:18

Yes ☐	
PC Time stamp	31 AUG 2020 18:19
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3572086

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

Was Contact Attempted? Yes ☒ No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 SEP 2020

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

Comments PATIENT REQUESTED SPANISH SPEAKING NURSE.

If Contact Not Made, please provide Comments

9/3/2020 AT 2:13 PM: SPOKE TO PATIENT IN SPANISH FOR SAFETY CALL. PATIENT REPORTED NO ADVERSE EVENTS; NO NEW MEDICATIONS; NO QUESTIONS AT THIS TIME. (b) (6)

US3572086

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572086

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 SEP 2020

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

Comments SUBJECT REPORTS DOING
WELL. NO AES OR NEW
If Contact Not Made, please provide Comments SYMPTOMS REPORTED.

US3572086

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572086

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments SUBJECT REPORTS DOING
WELL. NO AES OR NEW
SYMPTOMS REPORTED.
If Contact Not Made, please provide Comments

US3572086

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572086

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	23 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	09:00 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 09:00
Temperature (xxx.x)	98.1 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	10:33 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 10:33
Temperature (xxx.x)	97.3 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	156 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3572086

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 2020

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

US3572086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

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) 23 SEP 2020

What was the treatment time? (00:00-23:59) 10:03 (24 HR)

Treatment Date and Time (derived) 23 SEP 2020 10:03

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

US3572086

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	23 SEP 2020
Collection time (00:00-23:59)	9:10 (24 HR)
Collection date and time (derived)	23 SEP 2020 9:10

US3572086

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:06	23 SEP 2020 09:06
Nasopharyngeal Swab 2	No		

US3572086

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

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

23 SEP 2020 10:36

PC Open Date & Time

23 SEP 2020 10:23

PC Close Date & Time

23 SEP 2020 12:53

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

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

97.8 °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	23 SEP 2020 18:36
PC Open Date & Time	23 SEP 2020 13:48
PC Close Date & Time	24 SEP 2020 11:59

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 18:37

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 18:35

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

26 SEP 2020 18:51

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:18

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

97.8 °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

27 SEP 2020 19:35

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

28 SEP 2020 18:41

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

29 SEP 2020 18:10

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

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

23 SEP 2020 10:37

PC Open Date & Time

23 SEP 2020 10:23

PC Close Date & Time

23 SEP 2020 12:53

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

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

23 SEP 2020 18:36

PC Open Date & Time

23 SEP 2020 13:48

PC Close Date & Time

24 SEP 2020 11:59

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:18

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

24 SEP 2020 18:37

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:18

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

25 SEP 2020 18:34

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:18

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

26 SEP 2020 18:50

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:18

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

27 SEP 2020 19:34

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:18

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

28 SEP 2020 18:41

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:18

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

29 SEP 2020 18:09

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

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 ☐

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 10:37
PC Open Date & Time	23 SEP 2020 10:23
PC Close Date & Time	23 SEP 2020 12:53

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

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 ☐

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 18:37
PC Open Date & Time	23 SEP 2020 13:48
PC Close Date & Time	24 SEP 2020 11:59

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:18

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

EAB) (1725)

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US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:18

Yes ☐	
PC Time stamp	24 SEP 2020 18:37
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:18

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 ☒

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EAB) (1725)

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:18

Yes ☐	
PC Time stamp	25 SEP 2020 18:35
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:18

Yes ☐	
PC Time stamp	26 SEP 2020 18:50
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:18

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 ☒

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EAB) (1725)

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:18

Yes ☐	
PC Time stamp	27 SEP 2020 19:34
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:18

Yes ☐	
PC Time stamp	28 SEP 2020 18:41
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:18

Yes ☐	
PC Time stamp	29 SEP 2020 18:09
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3572086

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

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

US3572086

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572086

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572086

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572086

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572086

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572086

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	22 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3572086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	22 OCT 2020
Time of assessment (00:00-23:59)	09:05 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 09:05
Temperature (xxx.x)	97.5 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3572086

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 OCT 2020

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

US3572086

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	22 OCT 2020
Collection time (00:00-23:59)	09:20 (24 HR)
Collection date and time (derived)	22 OCT 2020 09:20

US3572086

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 04:23:13

Generated On: 10 Jun 2021 08:18:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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

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

Date and time of submission

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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

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

Date and time of submission

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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 ☐

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

Date and time of submission

21 NOV 2020 19:00:15

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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	26 NOV 2020 18:09:47
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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

03 DEC 2020 18:59:00

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 DEC 2020 18:24:00

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 18:42:18

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 DEC 2020 19:19:17

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 DEC 2020 18:51:58

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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 ☐

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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

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

Date and time of submission

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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):	
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 ☐

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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

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

Date and time of submission

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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

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

Date and time of submission

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3572086

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:18:18

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

US3572086

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 04:13:12

Generated On: 10 Jun 2021 08:18:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572086

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 04:13:12

Generated On: 10 Jun 2021 08:18:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572086

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:25:34

Generated On: 10 Jun 2021 08:18:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572086

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:25:34

Generated On: 10 Jun 2021 08:18:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572086

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 13 Apr 2021 04:31:46

Generated On: 10 Jun 2021 08:18:18

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 JAN 2021

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

Comments SUBJECT AT NURSING HOME
DUE TO STROKE. HE TESTED (+)
If Contact Not Made, please provide Comments FOR COVID 19.

US3572086

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:25:34

Generated On: 10 Jun 2021 08:18:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572086

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 10:05:02

Generated On: 10 Jun 2021 08:18:18

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572086

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:25:34

Generated On: 10 Jun 2021 08:18:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572086

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:18

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	_____

US3572086

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

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)	

US3572086

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:18

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.

US3572086

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:18

Was the sample collected?	Yes ☐
	No ☐

Collection date (<i>dd MMM yyyy</i>)	_____
Collection time (<i>00:00-23:59</i>)	_____
Collection date and time (derived)	_____

US3572086

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:18

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

Date of Contact 13 JAN 2021

Time of Contact

Date and Time of Contact (derived)

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 ☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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

Date	03 JAN 2021

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

	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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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

Date	04 JAN 2021

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

	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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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

Date	05 JAN 2021

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

	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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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

Date	6 JAN 2021

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

	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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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

Date	7 JAN 2021

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

	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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	8 JAN 2021	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

	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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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

Date	9 JAN 2021

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

	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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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

Date	10 JAN 2021

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

	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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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

Date	11 JAN 2021

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

	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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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

Date	12 APR 2021

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

	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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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

Date	13 JAN 2021

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

	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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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	☐

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

Date of Visit	3 JAN 2021
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	3 JAN 2021
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	LAREDO MEDICAL CENTER
CLIA Certified?	Yes ☒ No ☐
COVID-19 Positive (CSA Programming Field Only)	1

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

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

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

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

Ventilator Support:

High-Flow Oxygen? Yes ☐
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐
No ☐

Start Date

End Date

ECMO? Yes ☐
No ☐

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐
No ☐

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐
No ☐

Start Date

End Date

Acute Renal Dysfunction? Yes ☐
No ☐

Start Date

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

Hepatic Dysfunction? Yes ☐
No ☐

Start Date

Neurologic Dysfunction? Yes ☐
No ☐

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☐

Date of Assessment

Radiographical Evidence Yes ☐
No ☐

Date of Assessment

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

Start Date

End Date

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 28 Apr 2021 10:05:01

Generated On: 10 Jun 2021 08:18:18

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3572086

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

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 04:25:34

Generated On: 10 Jun 2021 08:18:18

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 UNBLND_DECIDE

US3572086

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

Form: Unblinding

Data signed: (b) (4) 15 Apr 2021 19:13:53

Generated On: 10 Jun 2021 08:18:18

Date of updated informed consent (<i>dd MMM yyyy</i>)	25 AUG 2020
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 (<i>dd MMM yyyy</i>)	30 MAR 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	1
Continuing with mRNA-1273	

US3572086

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 04:25:34

Generated On: 10 Jun 2021 08:18:18

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3572086

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 03 Apr 2021 04:25:34

Generated On: 10 Jun 2021 08:18:18

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00 - 23:59)

Collection Date and Time (derived)

US3572086

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 03 Apr 2021 04:25:33

Generated On: 10 Jun 2021 08:18:18

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 16:37:40

Generated On: 10 Jun 2021 08:18:18

AEID

Adverse event

WORSENING OF
HYPERTENSION

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)

23 SEP 2020

Start time (00:00-23:59)

09:00 (24 HR)

AE start date and time (derived)

23 SEP 2020 09:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 16:37:40

Generated On: 10 Jun 2021 08:18:18

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	
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)	

US3572086

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 16:37:40

Generated On: 10 Jun 2021 08:18:18

AEID	USA-US091-2021-MRNA-1273-P30 1000001
Adverse event	CVA
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)	31 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	13 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	3 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	13 JAN 2021
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 16:37:40

Generated On: 10 Jun 2021 08:18:18

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

US3572086

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 16:37:40

Generated On: 10 Jun 2021 08:18:18

THE SUBJECT PRESENTED TO THE HOSPITAL WITH HEADACHE, NECK PAIN, UPPER BACK PAIN, AND PELVIC PAIN STATUS POST FALL ONSET DEC 25, 2020. PATIENT DENIED LOC AND IS PRESENTING FACIAL DROOPING TO RIGHT SIDE OF FACE. THE SUBJECT WITH PAST MEDICAL HISTORY OF STROKE, HYPERTENSION AND HYPERLIPIDEMIA. WAS ADMITTED FOR PRESENTING NEUROLOGICAL SIGNS OF STROKE THAT HAVE BEEN PRESENT FOR 3 DAYS BEFORE ADMISSION. PATIENT WAS CONVINCED BY HIS CARE TAKER TO COME TO THE HOSPITAL. AFTER BEING ASSESSED IN THE ED, PATIENT WAS FOUND TO BE COVID 19 POSITIVE. PATIENT WAS ADMITTED TO THE COVID UNIT FOR SUPPORTIVE THERAPY AND NEUROLOGY WAS CONSULTED. DURING HOSPITALIZATION PATIENT REMAINED HEMODYNAMICALLY STABLE, STATED WEAKNESS AND MILD SOB FOR WHICH O2 SUPPLEMENT WAS PROVIDED WITH ALLEVIATION OF SYMPTOMS. SUSPICION FOR

US3572086

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 16:37:40

Generated On: 10 Jun 2021 08:18:18

SOME DECONDITIONING WAS
MADE, INCENTIVE
SPIROMETRY WAS ORDERED.
PATIENT RECEIVED
REMDESIVIR FOR 5 DAYS AND
CONVALESCENT PLASMA FOR
COVID19. PATIENT WAS
DEEMED FOR DISCHARGE TO
LAREDO NURSING AND REHAB
FOR ONGOING PT/OT. PATIENT
WILL CONTINUE CURRENT
TREATMENT AT THIS MOMENT
AND WILL BENEFIT FROM
REHABILITATION.

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

US3572086

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 16:37:40

Generated On: 10 Jun 2021 08:18:18

AEID	
Adverse event	PNEUMONIA
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 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	13 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 16:37:40

Generated On: 10 Jun 2021 08:18:18

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)	_____

US3572086

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 16:37:40

Generated On: 10 Jun 2021 08:18:18

AEID	USA-US091-2021-MRNA-1273-P30 1000015
Adverse event	COVID-19
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☒ No ☐
Start date (dd MMM yyyy)	3 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	12 FEB 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	True
Hospital Admission Date (dd MMM yyyy)	23 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	12 FEB 2021
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 16:37:40

Generated On: 10 Jun 2021 08:18:18

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☒ Not Recovered/Not Resolved ☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	@1407(REPORT OF DEATH) THE SITE RECEIVED A CALL FROM THE SUBJECTS NIECE TO INFORM US, SUBJECT HAS PASSED AWAY ON 12FEB2021.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 16:37:40

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

0

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 03 Apr 2021 04:25:33

Generated On: 10 Jun 2021 08:18:18

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

Yes ☒

No ☐

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

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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

Generated On: 10 Jun 2021 08:18:18

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication CVA

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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

Generated On: 10 Jun 2021 08:18:18

	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)	UN FEB 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	☒

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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

Generated On: 10 Jun 2021 08:18:18

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication FLU PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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

Generated On: 10 Jun 2021 08:18:18

	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)		21 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		21 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

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

Generated On: 10 Jun 2021 08:18:18

Name of Medication LEVONOX

Prophylaxis Yes ☐
No ☒

Indication CVA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

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

Generated On: 10 Jun 2021 08:18:18

	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)	3 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	12 FEB 2021	
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	☒

US3572086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 03 Apr 2021 04:25:34

Generated On: 10 Jun 2021 08:18:18

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3572086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 03 Apr 2021 04:25:33

Generated On: 10 Jun 2021 08:18:18

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
13 JAN 2021	PHYSICAL AND OCCUPATIONAL THERAPY FOLLOWING CVA	Adverse Event	
05 JAN 2021	COVID19 PLASMA	Other	COVID19 POSITIVE
01 JAN 2021	O2 SUPPLEMENT	Adverse Event	
01 JAN 2021	INCENTIVE SPIROMETRY	Adverse Event	
01 JAN 2021	REMDESIVIR ADMINISTERED FOR 5 DAYS	Adverse Event	

US3572086

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:18:18

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

US3572086

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 28 Apr 2021 10:05:02

Generated On: 10 Jun 2021 08:18:18

Date of study discontinuation/completion (dd MMM yyyy) 12 FEB 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) 12 FEB 2021

Was autopsy performed?

Yes	☐
No	☐
Unknown	☒

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 30 Apr 2021 16:37:40

Generated On: 10 Jun 2021 08:18:18

SAEID	USA-US091-2021-MRNA-1273-P301000001
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)	9

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Apr 2021 16:37:40

Generated On: 10 Jun 2021 08:18:18

SAEID	USA-US091-2021-MRNA-1273-P301000001
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)	9
Date of submission (Pre-filled from custom function)	20/JAN/2021 10:31
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

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 30 Apr 2021 16:37:40

Generated On: 10 Jun 2021 08:18:18

SAEID	USA-US091-2021-MRNA-1273-P301000001
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)	9
Date of submission (Pre-filled from custom function)	21/JAN/2021 14:38
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

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 30 Apr 2021 16:37:40

Generated On: 10 Jun 2021 08:18:18

SAEID	USA-US091-2021-MRNA-1273-P301000001
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)	9
Date of submission (Pre-filled from custom function)	03/FEB/2021 20:13
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

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 30 Apr 2021 16:37:40

Generated On: 10 Jun 2021 08:18:18

SAEID	USA-US091-2021-MRNA-1273-P301000001
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)	9
Date of submission (Pre-filled from custom function)	10/FEB/2021 16:44
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

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 30 Apr 2021 16:37:40

Generated On: 10 Jun 2021 08:18:18

SAEID	USA-US091-2021-MRNA-1273-P301000001
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)	9
Date of submission (Pre-filled from custom function)	11/FEB/2021 08:08
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

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 30 Apr 2021 16:37:40

Generated On: 10 Jun 2021 08:18:18

SAEID	USA-US091-2021-MRNA-1273-P301000001
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)	9
Date of submission (Pre-filled from custom function)	26/FEB/2021 14:44
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

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) 30 Apr 2021 16:37:40

Generated On: 10 Jun 2021 08:18:18

SAEID	USA-US091-2021-MRNA-1273-P301000001
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)	9
Date of submission (Pre-filled from custom function)	02/MAR/2021 08:34
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form (8)

Data signed: (b) (4) 30 Apr 2021 16:37:40

Generated On: 10 Jun 2021 08:18:18

SAEID	USA-US091-2021-MRNA-1273-P301000001
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)	9
Date of submission (Pre-filled from custom function)	04/MAR/2021 12:10
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form (9)

Data signed: (b) (4) 30 Apr 2021 16:37:40

Generated On: 10 Jun 2021 08:18:18

SAEID	USA-US091-2021-MRNA-1273-P301000001
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)	9
Date of submission (Pre-filled from custom function)	30/APR/2021 11:33
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

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 10:05:02

Generated On: 10 Jun 2021 08:18:18

SAEID	USA-US091-2021-MRNA-1273-P301000015
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)	5

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 10:05:02

Generated On: 10 Jun 2021 08:18:18

SAEID	USA-US091-2021-MRNA-1273-P301000015
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)	5
Date of submission (Pre-filled from custom function)	26/MAR/2021 22:47
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 10:05:02

Generated On: 10 Jun 2021 08:18:18

SAEID	USA-US091-2021-MRNA-1273-P301000015
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)	5
Date of submission (Pre-filled from custom function)	29/MAR/2021 11:30
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

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 10:05:02

Generated On: 10 Jun 2021 08:18:18

SAEID	USA-US091-2021-MRNA-1273-P301000015
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)	5
Date of submission (Pre-filled from custom function)	07/APR/2021 13:03
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

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 10:05:02

Generated On: 10 Jun 2021 08:18:18

SAEID	USA-US091-2021-MRNA-1273-P301000015
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)	5
Date of submission (Pre-filled from custom function)	15/APR/2021 14:40
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.	True

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 10:05:02

Generated On: 10 Jun 2021 08:18:18

SAEID	USA-US091-2021-MRNA-1273-P301000015
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)	5
Date of submission (Pre-filled from custom function)	26/APR/2021 13:08
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

US3572086 (Prod: Laguna Clinical Research Associates)

US3572086

Form: Participant Creation

Generated On: 10 Jun 2021 08:18:18

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered 'US3572086'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 15:34:47

US3572086

Form: Participant Creation

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:18:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4)	25 Aug 2020 16:27:03

US3572086

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered '25 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 15:34:48

US3572086

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:18:18

[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 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'Clinic (Clinic)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Aug 2020 16:27:03

US3572086

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:18:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User entered 'SCRN'	System	25 Aug 2020 16:27:03

US3572086

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:18

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered (b) (6) 1956'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 15:34:49

US3572086

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:18

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered '63'	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Aug 2020 16:28:32

US3572086

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:18

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User entered 'YEARS'	System	25 Aug 2020 16:28:32

US3572086

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:18

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User entered '63'	System	25 Aug 2020 16:29:27

US3572086

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:18

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'Male (M)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Aug 2020 16:28:32

US3572086

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:18

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4) (b) (4)	20 Mar 2021 23:49:17
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Alisha Lutat (b) (4) (b) (4)	25 Aug 2020 16:28:32

US3572086

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:18

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'l'	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Aug 2020 16:28:32

US3572086

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:18

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Aug 2020 16:28:32

US3572086

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:18

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Aug 2020 16:28:32

US3572086

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:18

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Aug 2020 16:28:32

US3572086

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:18

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Aug 2020 16:28:32

US3572086

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:18

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Aug 2020 16:28:32

US3572086

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:18

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered empty.	(b) (4) Alisha Lutat (b) (4)	25 Aug 2020 16:28:32

US3572086

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:18

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Aug 2020 16:28:32

US3572086

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:18

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered '0'	(b) (4) Alisha Lutat (b) (4)	25 Aug 2020 16:28:32

US3572086

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:18:18

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered '25 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Aug 2020 16:29:27

US3572086

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User entered 'Aug 2020'	System	25 Aug 2020 16:29:27

US3572086

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User entered '2020'	System	25 Aug 2020 16:29:27

US3572086

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:18:18

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'Amendment 3 (3)' reason for change:	(b) (4)	
Data Entry Error	Alisha Lutat (b) (4)	30 Aug 2020 18:37:21
User entered 'Amendment 2 (2)'	(b) (4)	
	Alisha Lutat (b) (4)	25 Aug 2020 16:29:27
	(b) (4)	

US3572086

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4)	25 Aug 2020 16:29:27

US3572086

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:18:18

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Aug 2020 16:29:27

US3572086

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:18:18

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Aug 2020 16:29:27

US3572086

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:18:18

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Aug 2020 16:29:27

US3572086

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:18:18

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 15:34:48

US3572086

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:18:18

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User entered 'l'	System	25 Aug 2020 16:29:42

US3572086

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Aug 2020 16:29:42

US3572086

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:18:18

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:38:27

US3572086

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: CVA - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	31 Aug 2020 04:50:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 04:50:44
Data point term sent to Coder	System	30 Aug 2020 18:40:45
User entered 'cerebrovascular-accident (CVA)'	Alisha Lutat (b) (4)	30 Aug 2020 18:40:31

US3572086

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'UN UNK 2004'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:40:31

US3572086

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:40:31

US3572086

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:40:31

US3572086

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'UN UNK 2004'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:40:31

US3572086

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:40:31

US3572086

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User entered 'Jan 2004'	System	30 Aug 2020 18:40:31

US3572086

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User entered '2004'	System	30 Aug 2020 18:40:31

US3572086

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User entered 'Jan 2004'	System	30 Aug 2020 18:40:31

US3572086

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User entered '2004'	System	30 Aug 2020 18:40:31

US3572086

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:18:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: CVA - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 04:50:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 04:50:44
Data point term sent to Coder	System	30 Aug 2020 18:41:45
User entered 'cerebrovascular-accident (CVA)'	Alisha Lutat (b) (4)	30 Aug 2020 18:41:10

US3572086

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'UN Feb 2020'	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 18:41:10

US3572086

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:18:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:41:10

US3572086

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:18:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:41:10

US3572086

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'UN Feb 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:41:10

US3572086

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:18:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:41:10

US3572086

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User entered 'Feb 2020'	System	30 Aug 2020 18:41:10

US3572086

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User entered '2020'	System	30 Aug 2020 18:41:10

US3572086

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User entered 'Feb 2020'	System	30 Aug 2020 18:41:10

US3572086

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User entered '2020'	System	30 Aug 2020 18:41:10

US3572086

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User closed query 'Per DM CLR-RQ: Response is conmed added. However, No CM recorded for hypertension in the CM eCRF. Please review and provide conmed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (u) (4), (b) (6)	28 Jan 2021 09:21:51
Query 'Per DM CLR-RQ: Response is conmed added. However, No CM recorded for hypertension in the CM eCRF. Please review and provide conmed as appropriate. Otherwise, provide clarification.' answered with 'no conmed reported in source for hypertension' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 05:36:10
User opened query 'Per DM CLR-RQ: Response is conmed added. However, No CM recorded for hypertension in the CM eCRF. Please review and provide conmed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 16:33:56
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	03 Nov 2020 04:30:35
' (Site from DM).		
Query 'Per DM CLR: Please note that there is no Con Alisha Lutat Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4) (b) (4)	28 Oct 2020 22:42:34
' answered with 'Source reviewed; con med added ' (Site from DM).		
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	28 Sep 2020 10:07:53
' (Site from DM).		

US3572086

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:18

Condition

Audit	User	Time (GMT)
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)	30 Aug 2020 18:42:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Aug 2020 18:42:38
Data point term sent to Coder	System	30 Aug 2020 18:41:45
User entered 'Hypertension'	Alisha Lutat (b) (4)	30 Aug 2020 18:41:37

US3572086

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'UN UNK 2004'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:41:37

US3572086

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:41:37

US3572086

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:41:37

US3572086

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:41:37

US3572086

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:41:37

US3572086

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User entered 'Jan 2004'	System	30 Aug 2020 18:41:37

US3572086

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User entered '2004'	System	30 Aug 2020 18:41:37

US3572086

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User entered empty.	System	30 Aug 2020 18:41:37

US3572086

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User entered empty.	System	30 Aug 2020 18:41:37

US3572086

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	02 Mar 2021 23:46:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Mar 2021 23:46:47
Data point term sent to Coder	System	02 Mar 2021 23:45:43
User entered 'HYPERLIPIDEMIA'	(b) (4), (b) (6)	02 Mar 2021 23:44:48

US3572086

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered empty.	(b) (4) (u) (4), (b) (6)	02 Mar 2021 23:44:48

US3572086

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'l'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 23:44:48

US3572086

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 23:44:48

US3572086

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered empty.	(b) (4) (u) (4), (b) (6)	02 Mar 2021 23:44:48

US3572086

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered '0'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 23:44:48

US3572086

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User entered empty.	System	02 Mar 2021 23:44:48

US3572086

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User entered empty.	System	02 Mar 2021 23:44:48

US3572086

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User entered empty.	System	02 Mar 2021 23:44:48

US3572086

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User entered empty.	System	02 Mar 2021 23:44:48

US3572086

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 18:42:54

US3572086

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered '25 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:42:54

US3572086

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered '10:54'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:42:54

US3572086

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User entered '25 Aug 2020 10:54'	System	30 Aug 2020 18:42:54

US3572086

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered '65' in	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 18:42:54
DataPoint set to visible.	(b) (4) System	25 Aug 2020 16:29:42

US3572086

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered '189' lb	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 18:42:54
DataPoint set to visible.	(b) (4) System	25 Aug 2020 16:29:42

US3572086

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User entered '31.51701'	System	30 Aug 2020 18:42:54
DataPoint set to visible.	System	25 Aug 2020 16:29:42

US3572086

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User entered 'kg/m2'	System	30 Aug 2020 18:42:54
DataPoint set to visible.	System	25 Aug 2020 16:29:42

US3572086

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 18:42:54

US3572086

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:42:54

US3572086

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:42:54

US3572086

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 18:42:54

US3572086

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User entered 'bpm'	System	30 Aug 2020 18:42:54

US3572086

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 18:42:54

US3572086

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User entered 'breaths/min'	System	30 Aug 2020 18:42:54

US3572086

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 18:42:54

US3572086

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User entered 'mmHg'	System	30 Aug 2020 18:42:54

US3572086

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 18:42:54

US3572086

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User entered 'mmHg'	System	30 Aug 2020 18:42:54

US3572086

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19

US3572086

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19

US3572086

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:43:52

US3572086

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:18

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered '25 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:43:52

US3572086

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:18

[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 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:45:51

US3572086

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:18

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 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:45:51

US3572086

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:18

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 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 18:45:51

US3572086

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:18

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 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Aug 2020 18:46:00
User entered 'No (N)' reason for change: Data Entry Error	Alisha Lutat (b) (4)	30 Aug 2020 18:46:00
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	30 Aug 2020 18:45:51
	Alisha Lutat (b) (4)	30 Aug 2020 18:45:51
	(b) (4)	

US3572086

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:18

[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 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:45:51

US3572086

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:18

[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 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:45:51

US3572086

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:18

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 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:45:51

US3572086

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:18

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 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:45:51

US3572086

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:18

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 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:45:51

US3572086

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:18

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 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:45:51

US3572086

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:18

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 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:45:51

US3572086

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:18

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:45:51

US3572086

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:18

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'Disabled/ retired'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:45:51

US3572086

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:18

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:45:51

US3572086

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:45:51

US3572086

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:18

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 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:45:51

US3572086

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:18

[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 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:45:51

US3572086

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:18

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 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered '0'	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 18:45:51

US3572086

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered 'l'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:45:51

US3572086

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:18

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:45:51

US3572086

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:18

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:57:19
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:49:17
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:45:51

US3572086

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:18:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Aug 2020 16:29:59

US3572086

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:18:18

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '25 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Aug 2020 16:29:59

US3572086

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Clinic (Clinic)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Aug 2020 16:29:59

US3572086

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:18:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'VISIT1'	System	25 Aug 2020 16:29:59

US3572086

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '25 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 15:54:55

US3572086

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '144837'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 15:54:55

US3572086

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 15:54:55

US3572086

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:18:18

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Aug 2020 16:30:19

US3572086

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4)	25 Aug 2020 16:30:19

US3572086

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Aug 2020 16:30:19

US3572086

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:18:18

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Aug 2020 16:30:19

US3572086

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:18:18

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Aug 2020 16:30:19

US3572086

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	14 Oct 2020 14:57:17
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 02:51:41
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:51:40

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:18

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:18

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User accepted default value 'Pre-Dose (PREDOSE)'	Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '25 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '10:54'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered '25 Aug 2020 10:54'	System	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '98.1' F	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Other (Other)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Temporal'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '84'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'bpm'	System	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '18'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'breaths/min'	System	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (u) (4), (b) (6)	31 Aug 2020 14:16:30
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:49:39
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	30 Aug 2020 18:48:12
User entered '157'	Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'mmHg'	System	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '85'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'mmHg'	System	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:18

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User accepted default value 'Post-Dose (POSTDOSE)'	Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '25 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '11:40'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered '25 Aug 2020 11:40'	System	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '98.1' F	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Other (Other)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Temporal'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '83'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'bpm'	System	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '18'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'breaths/min'	System	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '146'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'mmHg'	System	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '78'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'mmHg'	System	30 Aug 2020 18:48:12

US3572086

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:49:48

US3572086

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:18

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:49:48

US3572086

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:18:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Aug 2020 16:30:49

US3572086

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:18:18

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered empty.	(b) (4) Alisha Lutat (b) (4)	25 Aug 2020 16:30:49

US3572086

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Aug 2020 16:30:49

US3572086

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:18:18

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'MRNA-1273 OR PLACEBO'	System	25 Aug 2020 16:30:49

US3572086

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:18:18

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '25 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Aug 2020 16:30:49

US3572086

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '11:10'	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Aug 2020 16:30:49

US3572086

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered '25 Aug 2020 11:10'	System	25 Aug 2020 16:30:49

US3572086

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	25 Aug 2020 16:30:49

US3572086

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:18:18

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'ONCE'	System	25 Aug 2020 16:30:49

US3572086

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:18:18

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'INTRAMUSCULAR'	System	25 Aug 2020 16:30:49

US3572086

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:50:11

US3572086

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '25 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:50:11

US3572086

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '10:55'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:50:11

US3572086

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered '25 Aug 2020 10:55'	System	30 Aug 2020 18:50:11

US3572086

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:18:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '25 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:50:39

US3572086

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:18:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:50:39

US3572086

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:18:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:50:39

US3572086

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:18:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '11:03'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:50:39

US3572086

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered '25 Aug 2020 11:03'	System	30 Aug 2020 18:50:39

US3572086

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:18:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:50:39

US3572086

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:18:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:50:39

US3572086

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:18:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:50:39

US3572086

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered empty.	System	30 Aug 2020 18:50:39

US3572086

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:50:48

US3572086

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:18:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'l'	System	30 Aug 2020 18:50:48

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	25 Aug 2020 16:30:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T11:56:06', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'a209f6c9-a7e0-4cd2-8b56-d4ae4f70a1e3'	System	25 Aug 2020 16:56:18
User entered 'Yes (Y)'	System	25 Aug 2020 16:56:18

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T11:56:10', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'a209f6c9-a7e0-4cd2-8b56-d4ae4f70a1e3' User entered '98.1'	System	25 Aug 2020 16:56:18
	System	25 Aug 2020 16:56:18

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T11:56:15', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'a209f6c9-a7e0-4cd2-8b56-d4ae4f70a1e3'	System	25 Aug 2020 16:56:18
User entered 'No (N)'	System	25 Aug 2020 16:56:18

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T11:56:17', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'a209f6c9-a7e0-4cd2-8b56-d4ae4f70a1e3'	System	25 Aug 2020 16:56:18
User entered '25 Aug 2020 11:56'	System	25 Aug 2020 16:56:18

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '25 Aug 2020 11:30'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '25 Aug 2020 14:00'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	25 Aug 2020 16:30:49
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T18:02:46', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'a08406dd-70b1-4570-b378-79d56b8d0782'	System	25 Aug 2020 23:03:11
User entered 'Yes (Y)'	System	25 Aug 2020 23:03:11

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T18:02:56', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'a08406dd-70b1-4570-b378-79d56b8d0782' User entered '98.0'	System	25 Aug 2020 23:03:11
	System	25 Aug 2020 23:03:11

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T18:03:04', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'a08406dd-70b1-4570-b378-79d56b8d0782'	System	25 Aug 2020 23:03:11
User entered 'No (N)'	System	25 Aug 2020 23:03:11

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T18:03:08', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'a08406dd-70b1-4570-b378-79d56b8d0782'	System	25 Aug 2020 23:03:11
User entered '25 Aug 2020 18:03'	System	25 Aug 2020 23:03:11

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '25 Aug 2020 14:55'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	25 Aug 2020 16:30:49
User entered 'Day 2'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-26T18:43:23', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'ad46f482-bb6a-41e7-a1f4-add28024a2f8' User entered 'Yes (Y)'	System	26 Aug 2020 23:43:39
	System	26 Aug 2020 23:43:39

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-26T18:43:29', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'ad46f482-bb6a-41e7-a1f4-add28024a2f8' User entered '98.2'	System	26 Aug 2020 23:43:39
	System	26 Aug 2020 23:43:39

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-26T18:43:35', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'ad46f482-bb6a-41e7-a1f4-add28024a2f8'	System	26 Aug 2020 23:43:39
User entered 'No (N)'	System	26 Aug 2020 23:43:39

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-26T18:43:38', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'ad46f482-bb6a-41e7-a1f4-add28024a2f8'	System	26 Aug 2020 23:43:39
User entered '26 Aug 2020 18:43'	System	26 Aug 2020 23:43:39

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	25 Aug 2020 16:30:49
User entered 'Day 3'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-27T18:50:28', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'ba977a39-cb6b-441f-bc9e-f723d1f42441' User entered 'Yes (Y)'	System	27 Aug 2020 23:50:44
	System	27 Aug 2020 23:50:44

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-27T18:50:32', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'ba977a39-cb6b-441f-bc9e-f723d1f42441' User entered '97.5'	System	27 Aug 2020 23:50:44
	System	27 Aug 2020 23:50:44

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-27T18:50:38', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'ba977a39-cb6b-441f-bc9e-f723d1f42441'	System	27 Aug 2020 23:50:44
User entered 'No (N)'	System	27 Aug 2020 23:50:44

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-27T18:50:41', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'ba977a39-cb6b-441f-bc9e-f723d1f42441'	System	27 Aug 2020 23:50:44
User entered '27 Aug 2020 18:50'	System	27 Aug 2020 23:50:44

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	25 Aug 2020 16:30:49
User entered 'Day 4'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-28T18:46:01', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'f3203bf0-53fc-4b0b-8a91-e73cf038e347' User entered 'Yes (Y)'	System	28 Aug 2020 23:46:38
	System	28 Aug 2020 23:46:38

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-28T18:46:21', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'f3203bf0-53fc-4b0b-8a91-e73cf038e347' User entered '98.2'	System	28 Aug 2020 23:46:38
	System	28 Aug 2020 23:46:38

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-28T18:46:29', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'f3203bf0-53fc-4b0b-8a91-e73cf038e347'	System	28 Aug 2020 23:46:38
User entered 'No (N)'	System	28 Aug 2020 23:46:38

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-28T18:46:33', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'f3203bf0-53fc-4b0b-8a91-e73cf038e347'	System	28 Aug 2020 23:46:38
User entered '28 Aug 2020 18:46'	System	28 Aug 2020 23:46:38

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	25 Aug 2020 16:30:49
User entered 'Day 5'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-29T18:53:55', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'f3f590be-b74d-4f4e-a97a-51126d10c9ea' User entered 'Yes (Y)'	System	29 Aug 2020 23:54:05
	System	29 Aug 2020 23:54:05

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-29T18:53:58', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'f3f590be-b74d-4f4e-a97a-51126d10c9ea' User entered '98.1'	System	29 Aug 2020 23:54:05
	System	29 Aug 2020 23:54:05

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-29T18:54:00', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'f3f590be-b74d-4f4e-a97a-51126d10c9ea'	System	29 Aug 2020 23:54:05
User entered 'No (N)'	System	29 Aug 2020 23:54:05

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-29T18:54:03', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'f3f590be-b74d-4f4e-a97a-51126d10c9ea' User entered '29 Aug 2020 18:54'	System	29 Aug 2020 23:54:05
	System	29 Aug 2020 23:54:05

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	25 Aug 2020 16:30:49
User entered 'Day 6'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-30T19:36:53', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'eb55528f-0646-4c65-b876-fc7f0d08ecbd' User entered 'Yes (Y)'	System	31 Aug 2020 00:39:17
	System	31 Aug 2020 00:39:17

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-30T19:37:07', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'eb55528f-0646-4c65-b876-fc7f0d08ecbd' User entered '97.5'	System	31 Aug 2020 00:39:17
	System	31 Aug 2020 00:39:17

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-30T19:37:13', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'eb55528f-0646-4c65-b876-fc7f0d08ecbd' User entered 'No (N)'	System	31 Aug 2020 00:39:17
	System	31 Aug 2020 00:39:17

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-30T19:37:14', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'eb55528f-0646-4c65-b876-fc7f0d08ecbd' User entered '30 Aug 2020 19:37'	System	31 Aug 2020 00:39:17
	System	31 Aug 2020 00:39:17

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	25 Aug 2020 16:30:49
User entered 'Day 7'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-31T18:19:11', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '56b0b9c1-12a5-4ace-9e52-27ebc6bd6007' User entered 'Yes (Y)'	System	31 Aug 2020 23:19:24
	System	31 Aug 2020 23:19:24

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-31T18:19:15', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '56b0b9c1-12a5-4ace-9e52-27ebc6bd6007' User entered '98.2'	System	31 Aug 2020 23:19:24
	System	31 Aug 2020 23:19:24

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-31T18:19:19', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '56b0b9c1-12a5-4ace-9e52-27ebc6bd6007'	System	31 Aug 2020 23:19:24
User entered 'No (N)'	System	31 Aug 2020 23:19:24

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-31T18:19:21', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '56b0b9c1-12a5-4ace-9e52-27ebc6bd6007' User entered '31 Aug 2020 18:19'	System	31 Aug 2020 23:19:24
	System	31 Aug 2020 23:19:24

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	25 Aug 2020 16:30:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T11:56:23', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '42c4d1a0-47c7-4b7e-82e4-02715cad78b4' User entered 'None (1)'	System	25 Aug 2020 16:56:37
	System	25 Aug 2020 16:56:37

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T11:56:29', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '42c4d1a0-47c7-4b7e-82e4-02715cad78b4' User entered 'No (N)'	System	25 Aug 2020 16:56:37
	System	25 Aug 2020 16:56:37

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T11:56:31', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '42c4d1a0-47c7-4b7e-82e4-02715cad78b4' User entered 'No (N)'	System	25 Aug 2020 16:56:37
	System	25 Aug 2020 16:56:37

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T11:56:33', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '42c4d1a0-47c7-4b7e-82e4-02715cad78b4' User entered 'None (1)'	System	25 Aug 2020 16:56:37
	System	25 Aug 2020 16:56:37

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T11:56:35', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '42c4d1a0-47c7-4b7e-82e4-02715cad78b4' User entered '25 Aug 2020 11:56'	System	25 Aug 2020 16:56:37
	System	25 Aug 2020 16:56:37

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '25 Aug 2020 11:30'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '25 Aug 2020 14:00'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	25 Aug 2020 16:30:49
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T18:03:34', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '108cd82a-fb03-4699-9c8b-4897390c9988' User entered 'None (1)'	System	25 Aug 2020 23:03:57
	System	25 Aug 2020 23:03:57

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T18:03:38', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '108cd82a-fb03-4699-9c8b-4897390c9988' User entered 'No (N)'	System	25 Aug 2020 23:03:57
	System	25 Aug 2020 23:03:57

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T18:03:44', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '108cd82a-fb03-4699-9c8b-4897390c9988' User entered 'No (N)'	System	25 Aug 2020 23:03:57
	System	25 Aug 2020 23:03:57

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T18:03:53', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '108cd82a-fb03-4699-9c8b-4897390c9988'	System	25 Aug 2020 23:03:57
User entered 'None (1)'	System	25 Aug 2020 23:03:57

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T18:03:56', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '108cd82a-fb03-4699-9c8b-4897390c9988' User entered '25 Aug 2020 18:03'	System	25 Aug 2020 23:03:57
	System	25 Aug 2020 23:03:57

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '25 Aug 2020 14:55'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	25 Aug 2020 16:30:49
User entered 'Day 2'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-26T18:43:41', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '1816a61e-1f1e-4483-87a4-c33b62b7c8d5'	System	26 Aug 2020 23:43:52
User entered 'None (1)'	System	26 Aug 2020 23:43:52

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-26T18:43:44', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '1816a61e-1f1e-4483-87a4-c33b62b7c8d5'	System	26 Aug 2020 23:43:52
User entered 'No (N)'	System	26 Aug 2020 23:43:52

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-26T18:43:45', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '1816a61e-1f1e-4483-87a4-c33b62b7c8d5'	System	26 Aug 2020 23:43:52
User entered 'No (N)'	System	26 Aug 2020 23:43:52

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-26T18:43:47', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '1816a61e-1f1e-4483-87a4-c33b62b7c8d5'	System	26 Aug 2020 23:43:52
User entered 'None (1)'	System	26 Aug 2020 23:43:52

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-26T18:43:50', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '1816a61e-1f1e-4483-87a4-c33b62b7c8d5' User entered '26 Aug 2020 18:43'	System	26 Aug 2020 23:43:52
	System	26 Aug 2020 23:43:52

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	25 Aug 2020 16:30:49
User entered 'Day 3'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-27T18:50:45', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'f0730a3f-3aff-46dc-8a6f-bf42b6a8f47e'	System	27 Aug 2020 23:51:16
User entered 'None (1)'	System	27 Aug 2020 23:51:16

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-27T18:51:01', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'f0730a3f-3aff-46dc-8a6f-bf42b6a8f47e'	System	27 Aug 2020 23:51:16
User entered 'No (N)'	System	27 Aug 2020 23:51:16

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-27T18:51:09', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'f0730a3f-3aff-46dc-8a6f-bf42b6a8f47e'	System	27 Aug 2020 23:51:16
User entered 'No (N)'	System	27 Aug 2020 23:51:16

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-27T18:51:10', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'f0730a3f-3aff-46dc-8a6f-bf42b6a8f47e'	System	27 Aug 2020 23:51:16
User entered 'None (1)'	System	27 Aug 2020 23:51:16

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-27T18:51:13', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'f0730a3f-3aff-46dc-8a6f-bf42b6a8f47e'	System	27 Aug 2020 23:51:16
User entered '27 Aug 2020 18:51'	System	27 Aug 2020 23:51:16

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	25 Aug 2020 16:30:49
User entered 'Day 4'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-28T18:45:25', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '9724b0ef-0ca3-42a0-852e-74a57cb50649'	System	28 Aug 2020 23:45:36
User entered 'None (1)'	System	28 Aug 2020 23:45:36

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-28T18:45:27', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '9724b0ef-0ca3-42a0-852e-74a57cb50649'	System	28 Aug 2020 23:45:36
User entered 'No (N)'	System	28 Aug 2020 23:45:36

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-28T18:45:31', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '9724b0ef-0ca3-42a0-852e-74a57cb50649'	System	28 Aug 2020 23:45:36
User entered 'No (N)'	System	28 Aug 2020 23:45:36

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-28T18:45:32', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '9724b0ef-0ca3-42a0-852e-74a57cb50649'	System	28 Aug 2020 23:45:36
User entered 'None (1)'	System	28 Aug 2020 23:45:36

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-28T18:45:35', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '9724b0ef-0ca3-42a0-852e-74a57cb50649'	System	28 Aug 2020 23:45:36
User entered '28 Aug 2020 18:45'	System	28 Aug 2020 23:45:36

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	25 Aug 2020 16:30:49
User entered 'Day 5'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-29T18:54:06', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '76f1a2d5-cc98-4e16-a3d5-82091dda2aa7'	System	29 Aug 2020 23:54:15
User entered 'None (1)'	System	29 Aug 2020 23:54:15

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-29T18:54:09', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '76f1a2d5-cc98-4e16-a3d5-82091dda2aa7'	System	29 Aug 2020 23:54:15
User entered 'No (N)'	System	29 Aug 2020 23:54:15

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-29T18:54:11', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '76f1a2d5-cc98-4e16-a3d5-82091dda2aa7'	System	29 Aug 2020 23:54:15
User entered 'No (N)'	System	29 Aug 2020 23:54:15

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-29T18:54:12', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '76f1a2d5-cc98-4e16-a3d5-82091dda2aa7'	System	29 Aug 2020 23:54:15
User entered 'None (1)'	System	29 Aug 2020 23:54:15

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-29T18:54:14', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '76f1a2d5-cc98-4e16-a3d5-82091dda2aa7' User entered '29 Aug 2020 18:54'	System	29 Aug 2020 23:54:15
	System	29 Aug 2020 23:54:15

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	25 Aug 2020 16:30:49
User entered 'Day 6'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-30T19:35:30', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '2836d470-58f2-4b5c-a5cf-0b3360b4eec1' User entered 'None (1)'	System	31 Aug 2020 00:38:57
	System	31 Aug 2020 00:38:57

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-30T19:35:33', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '2836d470-58f2-4b5c-a5cf-0b3360b4eecd'	System	31 Aug 2020 00:38:57
User entered 'No (N)'	System	31 Aug 2020 00:38:57

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-30T19:35:36', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '2836d470-58f2-4b5c-a5cf-0b3360b4eecd'	System	31 Aug 2020 00:38:57
User entered 'No (N)'	System	31 Aug 2020 00:38:57

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-30T19:35:38', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '2836d470-58f2-4b5c-a5cf-0b3360b4eec1' User entered 'None (1)'	System	31 Aug 2020 00:38:57
	System	31 Aug 2020 00:38:57

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-30T19:35:41', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '2836d470-58f2-4b5c-a5cf-0b3360b4eecd'	System	31 Aug 2020 00:38:57
User entered '30 Aug 2020 19:35'	System	31 Aug 2020 00:38:57

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	25 Aug 2020 16:30:49
User entered 'Day 7'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-31T18:18:37', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '459afd7b-1615-464c-a10f-ae0903923139' User entered 'None (1)'	System	31 Aug 2020 23:18:47
	System	31 Aug 2020 23:18:47

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-31T18:18:39', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '459afd7b-1615-464c-a10f-ae0903923139' User entered 'No (N)'	System	31 Aug 2020 23:18:47
	System	31 Aug 2020 23:18:47

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-31T18:18:41', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '459afd7b-1615-464c-a10f-ae0903923139' User entered 'No (N)'	System	31 Aug 2020 23:18:47
	System	31 Aug 2020 23:18:47

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-31T18:18:43', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '459afd7b-1615-464c-a10f-ae0903923139' User entered 'None (1)'	System	31 Aug 2020 23:18:47
	System	31 Aug 2020 23:18:47

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-31T18:18:44', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '459afd7b-1615-464c-a10f-ae0903923139' User entered '31 Aug 2020 18:18'	System	31 Aug 2020 23:18:47
	System	31 Aug 2020 23:18:47

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	25 Aug 2020 16:30:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T11:56:39', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '6af7e033-671f-4279-8304-df3ee2a60b19'	System	25 Aug 2020 16:57:00
User entered 'None (0)'	System	25 Aug 2020 16:57:00

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T11:56:42', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '6af7e033-671f-4279-8304-df3ee2a60b19' User entered 'None (0)'	System	25 Aug 2020 16:57:00
	System	25 Aug 2020 16:57:00

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T11:56:46', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '6af7e033-671f-4279-8304-df3ee2a60b19' User entered 'None (0)'	System	25 Aug 2020 16:57:00
	System	25 Aug 2020 16:57:00

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T11:56:48', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '6af7e033-671f-4279-8304-df3ee2a60b19' User entered 'None (0)'	System	25 Aug 2020 16:57:00
	System	25 Aug 2020 16:57:00

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T11:56:51', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '6af7e033-671f-4279-8304-df3ee2a60b19'	System	25 Aug 2020 16:57:00
User entered 'None (0)'	System	25 Aug 2020 16:57:00

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T11:56:54', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '6af7e033-671f-4279-8304-df3ee2a60b19' User entered 'None (0)'	System	25 Aug 2020 16:57:00
	System	25 Aug 2020 16:57:00

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T11:56:57', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '6af7e033-671f-4279-8304-df3ee2a60b19'	System	25 Aug 2020 16:57:00
User entered 'No (N)'	System	25 Aug 2020 16:57:00

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T11:56:59', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '6af7e033-671f-4279-8304-df3ee2a60b19' User entered '25 Aug 2020 11:56'	System	25 Aug 2020 16:57:00
	System	25 Aug 2020 16:57:00

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '25 Aug 2020 11:30'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '25 Aug 2020 14:00'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	25 Aug 2020 16:30:49
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T18:04:01', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'aa2f389b-76ab-436d-a90e-552b9f4b931c' User entered 'None (0)'	System	25 Aug 2020 23:04:23
	System	25 Aug 2020 23:04:23

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T18:04:04', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'aa2f389b-76ab-436d-a90e-552b9f4b931c' User entered 'None (0)'	System	25 Aug 2020 23:04:23
	System	25 Aug 2020 23:04:23

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T18:04:07', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'aa2f389b-76ab-436d-a90e-552b9f4b931c' User entered 'None (0)'	System	25 Aug 2020 23:04:23
	System	25 Aug 2020 23:04:23

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T18:04:09', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'aa2f389b-76ab-436d-a90e-552b9f4b931c' User entered 'None (0)'	System	25 Aug 2020 23:04:23
	System	25 Aug 2020 23:04:23

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T18:04:12', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'aa2f389b-76ab-436d-a90e-552b9f4b931c' User entered 'None (0)'	System	25 Aug 2020 23:04:23
	System	25 Aug 2020 23:04:23

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T18:04:14', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'aa2f389b-76ab-436d-a90e-552b9f4b931c' User entered 'None (0)'	System	25 Aug 2020 23:04:23
	System	25 Aug 2020 23:04:23

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T18:04:17', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'aa2f389b-76ab-436d-a90e-552b9f4b931c' User entered 'No (N)'	System	25 Aug 2020 23:04:23
	System	25 Aug 2020 23:04:23

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-25T18:04:20', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'aa2f389b-76ab-436d-a90e-552b9f4b931c' User entered '25 Aug 2020 18:04'	System	25 Aug 2020 23:04:23
	System	25 Aug 2020 23:04:23

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '25 Aug 2020 14:55'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	25 Aug 2020 16:30:49
User entered 'Day 2'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-26T18:43:53', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '6afe8e19-a70d-4e89-9dd4-7510a24ebdd1' User entered 'None (0)'	System	26 Aug 2020 23:44:09
	System	26 Aug 2020 23:44:09

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-26T18:43:55', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '6afe8e19-a70d-4e89-9dd4-7510a24ebdd1' User entered 'None (0)'	System	26 Aug 2020 23:44:09
	System	26 Aug 2020 23:44:09

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-26T18:43:56', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '6afe8e19-a70d-4e89-9dd4-7510a24ebdd1' User entered 'None (0)'	System	26 Aug 2020 23:44:09
	System	26 Aug 2020 23:44:09

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-26T18:43:59', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '6afe8e19-a70d-4e89-9dd4-7510a24ebdd1' User entered 'None (0)'	System	26 Aug 2020 23:44:09
	System	26 Aug 2020 23:44:09

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-26T18:44:01', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '6afe8e19-a70d-4e89-9dd4-7510a24ebdd1' User entered 'None (0)'	System	26 Aug 2020 23:44:09
	System	26 Aug 2020 23:44:09

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-26T18:44:02', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '6afe8e19-a70d-4e89-9dd4-7510a24ebdd1' User entered 'None (0)'	System	26 Aug 2020 23:44:09
	System	26 Aug 2020 23:44:09

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-26T18:44:05', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '6afe8e19-a70d-4e89-9dd4-7510a24ebdd1' User entered 'No (N)'	System	26 Aug 2020 23:44:09
	System	26 Aug 2020 23:44:09

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-26T18:44:07', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '6afe8e19-a70d-4e89-9dd4-7510a24ebdd1' User entered '26 Aug 2020 18:44'	System	26 Aug 2020 23:44:09
	System	26 Aug 2020 23:44:09

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	25 Aug 2020 16:30:49
User entered 'Day 3'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-27T18:51:17', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '31ffa4a7-ec1a-41d2-9918-cab2325f634c' User entered 'None (0)'	System	27 Aug 2020 23:51:32
	System	27 Aug 2020 23:51:32

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-27T18:51:19', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '31ffa4a7-ec1a-41d2-9918-cab2325f634c' User entered 'None (0)'	System	27 Aug 2020 23:51:32
	System	27 Aug 2020 23:51:32

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-27T18:51:21', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '31ffa4a7-ec1a-41d2-9918-cab2325f634c' User entered 'None (0)'	System	27 Aug 2020 23:51:32
	System	27 Aug 2020 23:51:32

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-27T18:51:22', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '31ffa4a7-ec1a-41d2-9918-cab2325f634c' User entered 'None (0)'	System	27 Aug 2020 23:51:32
	System	27 Aug 2020 23:51:32

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-27T18:51:23', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '31ffa4a7-ec1a-41d2-9918-cab2325f634c' User entered 'None (0)'	System	27 Aug 2020 23:51:32
	System	27 Aug 2020 23:51:32

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-27T18:51:25', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '31ffa4a7-ec1a-41d2-9918-cab2325f634c' User entered 'None (0)'	System	27 Aug 2020 23:51:32
	System	27 Aug 2020 23:51:32

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-27T18:51:27', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '31ffa4a7-ec1a-41d2-9918-cab2325f634c' User entered 'No (N)'	System	27 Aug 2020 23:51:32
	System	27 Aug 2020 23:51:32

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-27T18:51:30', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '31ffa4a7-ec1a-41d2-9918-cab2325f634c' User entered '27 Aug 2020 18:51'	System	27 Aug 2020 23:51:32
	System	27 Aug 2020 23:51:32

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	25 Aug 2020 16:30:49
User entered 'Day 4'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-28T18:46:53', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '67983d5b-9b88-4b45-a4fc-6fbf92e6c8a2'	System	28 Aug 2020 23:47:12
User entered 'None (0)'	System	28 Aug 2020 23:47:12

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-28T18:46:57', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '67983d5b-9b88-4b45-a4fc-6fbf92e6c8a2'	System	28 Aug 2020 23:47:12
User entered 'None (0)'	System	28 Aug 2020 23:47:12

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-28T18:46:59', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '67983d5b-9b88-4b45-a4fc-6fbf92e6c8a2'	System	28 Aug 2020 23:47:12
User entered 'None (0)'	System	28 Aug 2020 23:47:12

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-28T18:47:00', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '67983d5b-9b88-4b45-a4fc-6fbf92e6c8a2' User entered 'None (0)'	System	28 Aug 2020 23:47:12
	System	28 Aug 2020 23:47:12

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-28T18:47:01', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '67983d5b-9b88-4b45-a4fc-6fbf92e6c8a2'	System	28 Aug 2020 23:47:12
User entered 'None (0)'	System	28 Aug 2020 23:47:12

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-28T18:47:02', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '67983d5b-9b88-4b45-a4fc-6fbf92e6c8a2'	System	28 Aug 2020 23:47:12
User entered 'None (0)'	System	28 Aug 2020 23:47:12

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-28T18:47:07', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '67983d5b-9b88-4b45-a4fe-6fbf92e6c8a2'	System	28 Aug 2020 23:47:12
User entered 'No (N)'	System	28 Aug 2020 23:47:12

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-28T18:47:08', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '67983d5b-9b88-4b45-a4fc-6fbf92e6c8a2'	System	28 Aug 2020 23:47:12
User entered '28 Aug 2020 18:47'	System	28 Aug 2020 23:47:12

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	25 Aug 2020 16:30:49
User entered 'Day 5'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-29T18:54:17', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'a8f6cc5d-8906-4a51-9835-1feecfb51876' User entered 'None (0)'	System	29 Aug 2020 23:54:34
	System	29 Aug 2020 23:54:34

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-29T18:54:18', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'a8f6cc5d-8906-4a51-9835-1feecfb51876' User entered 'None (0)'	System	29 Aug 2020 23:54:34
	System	29 Aug 2020 23:54:34

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-29T18:54:20', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'a8f6cc5d-8906-4a51-9835-1feecfb51876' User entered 'None (0)'	System	29 Aug 2020 23:54:34
	System	29 Aug 2020 23:54:34

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-29T18:54:21', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'a8f6cc5d-8906-4a51-9835-1feecfb51876' User entered 'None (0)'	System	29 Aug 2020 23:54:34
	System	29 Aug 2020 23:54:34

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-29T18:54:22', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'a8f6cc5d-8906-4a51-9835-1feecfb51876' User entered 'None (0)'	System	29 Aug 2020 23:54:34
	System	29 Aug 2020 23:54:34

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-29T18:54:24', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'a8f6cc5d-8906-4a51-9835-1feecfb51876' User entered 'None (0)'	System	29 Aug 2020 23:54:34
	System	29 Aug 2020 23:54:34

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-29T18:54:27', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'a8f6cc5d-8906-4a51-9835-1feecfb51876' User entered 'No (N)'	System	29 Aug 2020 23:54:34
	System	29 Aug 2020 23:54:34

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-29T18:54:29', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'a8f6cc5d-8906-4a51-9835-1feecfb51876' User entered '29 Aug 2020 18:54'	System	29 Aug 2020 23:54:34
	System	29 Aug 2020 23:54:34

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	25 Aug 2020 16:30:49
User entered 'Day 6'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-30T19:35:45', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '880de139-4dad-48dd-a972-6eed60647c28' User entered 'None (0)'	System	31 Aug 2020 00:39:05
	System	31 Aug 2020 00:39:05

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-30T19:35:47', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '880de139-4dad-48dd-a972-6eed60647c28' User entered 'None (0)'	System	31 Aug 2020 00:39:05
	System	31 Aug 2020 00:39:05

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-30T19:35:49', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '880de139-4dad-48dd-a972-6eed60647c28' User entered 'None (0)'	System	31 Aug 2020 00:39:05
	System	31 Aug 2020 00:39:05

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-30T19:35:51', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '880de139-4dad-48dd-a972-6eed60647c28' User entered 'None (0)'	System	31 Aug 2020 00:39:05
	System	31 Aug 2020 00:39:05

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-30T19:35:52', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '880de139-4dad-48dd-a972-6eed60647c28' User entered 'None (0)'	System	31 Aug 2020 00:39:05
	System	31 Aug 2020 00:39:05

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-30T19:35:54', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '880de139-4dad-48dd-a972-6eed60647c28' User entered 'None (0)'	System	31 Aug 2020 00:39:05
	System	31 Aug 2020 00:39:05

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-30T19:35:58', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '880de139-4dad-48dd-a972-6ced60647c28'	System	31 Aug 2020 00:39:05
User entered 'No (N)'	System	31 Aug 2020 00:39:05

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-30T19:36:00', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '880de139-4dad-48dd-a972-6eed60647c28' User entered '30 Aug 2020 19:36'	System	31 Aug 2020 00:39:05
	System	31 Aug 2020 00:39:05

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	25 Aug 2020 16:30:49
User entered 'Day 7'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-31T18:18:47', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'e8ed68c2-7301-43a8-849e-dc7233eb13f0' User entered 'None (0)'	System	31 Aug 2020 23:19:08
	System	31 Aug 2020 23:19:08

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-31T18:18:48', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'e8ed68c2-7301-43a8-849e-dc7233eb13f0' User entered 'None (0)'	System	31 Aug 2020 23:19:08
	System	31 Aug 2020 23:19:08

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-31T18:18:51', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'e8ed68c2-7301-43a8-849e-dc7233eb13f0' User entered 'None (0)'	System	31 Aug 2020 23:19:08
	System	31 Aug 2020 23:19:08

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-31T18:18:53', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'e8ed68c2-7301-43a8-849e-dc7233eb13f0' User entered 'None (0)'	System	31 Aug 2020 23:19:08
	System	31 Aug 2020 23:19:08

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-31T18:18:54', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'e8ed68c2-7301-43a8-849e-dc7233eb13f0' User entered 'None (0)'	System	31 Aug 2020 23:19:08
	System	31 Aug 2020 23:19:08

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-31T18:18:56', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'e8ed68c2-7301-43a8-849e-dc7233eb13f0' User entered 'None (0)'	System	31 Aug 2020 23:19:08
	System	31 Aug 2020 23:19:08

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-31T18:18:57', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'e8ed68c2-7301-43a8-849e-dc7233eb13f0'	System	31 Aug 2020 23:19:08
User entered 'No (N)'	System	31 Aug 2020 23:19:08

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-08-31T18:19:06', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'e8ed68c2-7301-43a8-849e-dc7233eb13f0'	System	31 Aug 2020 23:19:08
User entered '31 Aug 2020 18:19'	System	31 Aug 2020 23:19:08

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 16:30:49

US3572086

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 16:30:49

US3572086

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Yes (Y)'	(b) (4) Jasmine Ali (b) (4)	01 Sep 2020 14:34:13

US3572086

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '1 Sep 2020'	(b) (4) Jasmine Ali (b) (4) (b) (4)	01 Sep 2020 14:34:13

US3572086

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jasmine Ali (b) (4)	01 Sep 2020 14:34:13

US3572086

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'PATIENT REQUESTED SPANISH SPEAKING NURSE.'	(b) (4) (u) (4), (b) (6)	03 Sep 2020 19:13:56
9/3/2020 at 2:13 PM: Spoke to patient in Spanish for safety call. Patient reported no adverse events; no new medications; no questions at this time. (b) (6)		
reason for change: Data Entry Error		
User entered 'Patient requested Spanish speaking nurse.'	Jasmine Ali (b) (4) (b) (4)	01 Sep 2020 14:34:13

US3572086

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	03 Sep 2020 19:14:02

US3572086

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'l'	System	03 Sep 2020 19:14:02

US3572086

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	19 Sep 2020 21:21:23

US3572086

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '11 Sep 2020'	(b) (4) (u) (4), (b) (6)	19 Sep 2020 21:21:23

US3572086

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (u) (4), (b) (6)	19 Sep 2020 21:21:23

US3572086

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Subject reports doing well. No AEs or new symptoms reported.'	(b) (4) (u) (4), (b) (6)	19 Sep 2020 21:21:23

US3572086

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	19 Sep 2020 21:21:27

US3572086

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'l'	System	19 Sep 2020 21:21:27

US3572086

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23SEP2020 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 Nov 2020 12:55:38
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23SEP2020 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.	Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:33:11
' answered with 'data entered' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23SEP2020 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 05:31:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Sep 2020 21:22:05

US3572086

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '18 Sep 2020'	(b) (4) (u) (4), (b) (6)	19 Sep 2020 21:22:05

US3572086

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (u) (4), (b) (6)	19 Sep 2020 21:22:05

US3572086

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Subject reports doing well. No AEs or new symptoms reported.'	(b) (4) (u) (4), (b) (6)	19 Sep 2020 21:22:05

US3572086

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	19 Sep 2020 21:22:09

US3572086

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'l'	System	19 Sep 2020 21:22:09

US3572086

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:33:25

US3572086

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '23 Sep 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:33:25

US3572086

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Clinic (Clinic)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:33:25

US3572086

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'VISIT2'	System	28 Oct 2020 22:33:25

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User accepted default value 'Pre-Dose (PREDOSE)'	Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '23 Sep 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '09:00'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered '23 Sep 2020 09:00'	System	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '98.1' F	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Other (Other)'	(b) (4) Alisha Lutat (b) (4)	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'temporal'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '87'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'bpm'	System	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '20'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'breaths/min'	System	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '152'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'mmHg'	System	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '82'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'mmHg'	System	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User accepted default value 'Post-Dose (POSTDOSE)'	Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '23 Sep 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '10:33'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered '23 Sep 2020 10:33'	System	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '97.3' F	(b) (4) Alisha Lutat (b) (4)	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Other (Other)'	(b) (4) Alisha Lutat (b) (4)	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'temporal'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '79'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'bpm'	System	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '18'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'breaths/min'	System	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '156'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'mmHg'	System	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '85'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'mmHg'	System	28 Oct 2020 22:36:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:36:15

US3572086

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '23 Sep 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:36:15

US3572086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User closed query 'Per GCL Lab Recon: GCL has immunogenicity sample with date of 23 sep 20 however, sample (or visit) is not recorded in EDC. Please review and reconcile' (Site from DM).	(b) (4) (u) (4), (b) (6)	04 Nov 2020 12:53:14
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 23SEP2020 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 Nov 2020 11:23:04
Query 'Per GCL Lab Recon: GCL has immunogenicity sample with date of 23 sep 20 however, sample (or visit) is not recorded in EDC. Please review and reconcile' answered with 'data entered' (Site from DM).	Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:44:02
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 23SEP2020 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' answered with 'data entered' (Site from DM).	Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:43:54
User opened query 'Per GCL Lab Recon: GCL has immunogenicity sample with date of 23 sep 20 however, sample (or visit) is not recorded in EDC. Please review and reconcile' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 19:28:15
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 23SEP2020 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)	22 Oct 2020 07:45:31
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	23 Sep 2020 15:01:39

US3572086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:18

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	23 Sep 2020 15:01:39

US3572086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	23 Sep 2020 15:01:39

US3572086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:18

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 15:01:39

US3572086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:18

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '23 Sep 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	23 Sep 2020 15:01:39

US3572086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '10:03'	(b) (4) Alisha Lutat (b) (4) (b) (4)	23 Sep 2020 15:01:39

US3572086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered '23 Sep 2020 10:03'	System	23 Sep 2020 15:01:39

US3572086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4) System	23 Sep 2020 15:01:59
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	23 Sep 2020 15:01:59
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	Alisha Lutat (b) (4) (b) (4)	23 Sep 2020 15:01:59
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	23 Sep 2020 15:01:39
User entered 'Left Arm (LEFT ARM)'	Alisha Lutat (b) (4) (b) (4)	23 Sep 2020 15:01:39

US3572086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'ONCE'	System	23 Sep 2020 15:01:39

US3572086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:18

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 15:01:39

US3572086

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:36:40

US3572086

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '23 Sep 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:36:40

US3572086

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '9:10'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:36:40

US3572086

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered '23 Sep 2020 9:10'	System	28 Oct 2020 22:36:40

US3572086

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:18:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '23 Sep 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:37:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:18:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:37:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:18:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:37:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:18:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '09:06'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:37:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered '23 Sep 2020 09:06'	System	28 Oct 2020 22:37:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:18:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:37:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:18:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:37:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:18:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 22:37:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered empty.	System	28 Oct 2020 22:37:02

US3572086

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 17:57:04

US3572086

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'I'	System	01 Oct 2020 17:57:04

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	23 Sep 2020 15:01:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T10:36:02', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'efff4c42-bb17-4f5c-905b-db1642d2f851' User entered 'Yes (Y)'	System	23 Sep 2020 15:36:35
	System	23 Sep 2020 15:36:35

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T10:36:16', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'efff4c42-bb17-4f5c-905b-db1642d2f851' User entered '97.3'	System	23 Sep 2020 15:36:35
	System	23 Sep 2020 15:36:35

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T10:36:24', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'efff4c42-bb17-4f5c-905b-db1642d2f851'	System	23 Sep 2020 15:36:35
User entered 'No (N)'	System	23 Sep 2020 15:36:35

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T10:36:32', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'efff4c42-bb17-4f5c-905b-db1642d2f851'	System	23 Sep 2020 15:36:35
User entered '23 Sep 2020 10:36'	System	23 Sep 2020 15:36:35

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '23 Sep 2020 10:23'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '23 Sep 2020 12:53'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	23 Sep 2020 15:01:39
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T18:35:22', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'bc6ffb8b-0058-4a79-a607-5e341109dfbc' User entered 'Yes (Y)'	System	23 Sep 2020 23:36:11
	System	23 Sep 2020 23:36:11

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T18:35:59', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'bc6ffb8b-0058-4a79-a607-5e341109dfbc' User entered '97.8'	System	23 Sep 2020 23:36:11
	System	23 Sep 2020 23:36:11

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T18:36:03', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'bc6ffb8b-0058-4a79-a607-5e341109dfbc'	System	23 Sep 2020 23:36:11
User entered 'No (N)'	System	23 Sep 2020 23:36:11

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T18:36:08', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'bc6ffb8b-0058-4a79-a607-5e341109dfbc'	System	23 Sep 2020 23:36:11
User entered '23 Sep 2020 18:36'	System	23 Sep 2020 23:36:11

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '23 Sep 2020 13:48'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	23 Sep 2020 15:01:39
User entered 'Day 2'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-24T18:37:47', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '355f5df2-ba17-418d-91ff-b43d45ea838d' User entered 'Yes (Y)'	System	24 Sep 2020 23:38:04
	System	24 Sep 2020 23:38:04

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-24T18:37:50', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '355f5df2-ba17-418d-91ff-b43d45ea838d' User entered '98.0'	System	24 Sep 2020 23:38:04
	System	24 Sep 2020 23:38:04

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-24T18:37:53', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '355f5df2-ba17-418d-91ff-b43d45ea838d'	System	24 Sep 2020 23:38:04
User entered 'No (N)'	System	24 Sep 2020 23:38:04

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-24T18:37:57', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '355f5df2-ba17-418d-91ff-b43d45ea838d' User entered '24 Sep 2020 18:37'	System	24 Sep 2020 23:38:04
	System	24 Sep 2020 23:38:04

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	23 Sep 2020 15:01:39
User entered 'Day 3'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-25T18:35:05', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'c931ebc2-1e87-4d72-8298-6d9a32b77cb4' User entered 'Yes (Y)'	System	25 Sep 2020 23:35:21
	System	25 Sep 2020 23:35:21

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-25T18:35:12', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'c931ebc2-1e87-4d72-8298-6d9a32b77cb4' User entered '98.2'	System	25 Sep 2020 23:35:21
	System	25 Sep 2020 23:35:21

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-25T18:35:16', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'c931ebc2-1e87-4d72-8298-6d9a32b77cb4'	System	25 Sep 2020 23:35:21
User entered 'No (N)'	System	25 Sep 2020 23:35:21

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-25T18:35:18', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'c931ebc2-1e87-4d72-8298-6d9a32b77cb4' User entered '25 Sep 2020 18:35'	System	25 Sep 2020 23:35:21
	System	25 Sep 2020 23:35:21

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	23 Sep 2020 15:01:39
User entered 'Day 4'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-26T18:51:00', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'ff66aefb-a20b-4c0c-96a3-cc886cdfa0d9' User entered 'Yes (Y)'	System	26 Sep 2020 23:51:15
	System	26 Sep 2020 23:51:15

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-26T18:51:07', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'ff66aefb-a20b-4c0c-96a3-cc886cdfa0d9' User entered '98.6'	System	26 Sep 2020 23:51:15
	System	26 Sep 2020 23:51:15

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-26T18:51:11', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'ff66aefb-a20b-4c0c-96a3-cc886cdfa0d9'	System	26 Sep 2020 23:51:15
User entered 'No (N)'	System	26 Sep 2020 23:51:15

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-26T18:51:13', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'ff66aefb-a20b-4c0c-96a3-cc886cdfa0d9'	System	26 Sep 2020 23:51:15
User entered '26 Sep 2020 18:51'	System	26 Sep 2020 23:51:15

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	23 Sep 2020 15:01:39
User entered 'Day 5'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-27T19:34:56', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'ea88e8bb-1191-4d74-84fb-145533ccb50b' User entered 'Yes (Y)'	System	28 Sep 2020 00:35:08
	System	28 Sep 2020 00:35:08

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-27T19:35:01', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'ea88e8bb-1191-4d74-84fb-145533ccb50b' User entered '97.8'	System	28 Sep 2020 00:35:08
	System	28 Sep 2020 00:35:08

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-27T19:35:04', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'ea88e8bb-1191-4d74-84fb-145533ccb50b' User entered 'No (N)'	System	28 Sep 2020 00:35:08
	System	28 Sep 2020 00:35:08

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-27T19:35:05', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'ea88e8bb-1191-4d74-84fb-145533ccb50b' User entered '27 Sep 2020 19:35'	System	28 Sep 2020 00:35:08
	System	28 Sep 2020 00:35:08

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	23 Sep 2020 15:01:39
User entered 'Day 6'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-28T18:41:36', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '25d6f779-f66b-4376-b518-afdb956d08a9' User entered 'Yes (Y)'	System	28 Sep 2020 23:41:49
	System	28 Sep 2020 23:41:49

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-28T18:41:40', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '25d6f779-f66b-4376-b518-afdb956d08a9' User entered '98.8'	System	28 Sep 2020 23:41:49
	System	28 Sep 2020 23:41:49

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-28T18:41:42', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '25d6f779-f66b-4376-b518-afdb956d08a9' User entered 'No (N)'	System	28 Sep 2020 23:41:49
	System	28 Sep 2020 23:41:49

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-28T18:41:45', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '25d6f779-f66b-4376-b518-afdb956d08a9' User entered '28 Sep 2020 18:41'	System	28 Sep 2020 23:41:49
	System	28 Sep 2020 23:41:49

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	23 Sep 2020 15:01:39
User entered 'Day 7'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-29T18:09:54', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'bc17a9c8-99d1-4fa8-9ad9-4287b0ef317d' User entered 'Yes (Y)'	System	29 Sep 2020 23:10:09
	System	29 Sep 2020 23:10:09

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-29T18:10:01', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'bc17a9c8-99d1-4fa8-9ad9-4287b0ef317d' User entered '98.3'	System	29 Sep 2020 23:10:09
	System	29 Sep 2020 23:10:09

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-29T18:10:04', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'bc17a9c8-99d1-4fa8-9ad9-4287b0ef317d'	System	29 Sep 2020 23:10:09
User entered 'No (N)'	System	29 Sep 2020 23:10:09

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-29T18:10:06', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'bc17a9c8-99d1-4fa8-9ad9-4287b0ef317d' User entered '29 Sep 2020 18:10'	System	29 Sep 2020 23:10:09
	System	29 Sep 2020 23:10:09

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	23 Sep 2020 15:01:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T10:37:09', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'd9e98750-6886-4371-8cb7-0dc363a79046'	System	23 Sep 2020 15:37:34
User entered 'None (1)'	System	23 Sep 2020 15:37:34

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T10:37:14', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'd9e98750-6886-4371-8cb7-0dc363a79046' User entered 'No (N)'	System	23 Sep 2020 15:37:34
	System	23 Sep 2020 15:37:34

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T10:37:19', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'd9e98750-6886-4371-8cb7-0dc363a79046'	System	23 Sep 2020 15:37:34
User entered 'No (N)'	System	23 Sep 2020 15:37:34

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T10:37:24', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'd9e98750-6886-4371-8cb7-0dc363a79046'	System	23 Sep 2020 15:37:34
User entered 'None (1)'	System	23 Sep 2020 15:37:34

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T10:37:29', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'd9e98750-6886-4371-8cb7-0dc363a79046'	System	23 Sep 2020 15:37:34
User entered '23 Sep 2020 10:37'	System	23 Sep 2020 15:37:34

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '23 Sep 2020 10:23'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '23 Sep 2020 12:53'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	23 Sep 2020 15:01:39
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T18:36:27', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '0edad6e2-ddbd-4468-ba2a-e52a39c9a4d5'	System	23 Sep 2020 23:36:40
User entered 'None (1)'	System	23 Sep 2020 23:36:40

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T18:36:30', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '0edad6e2-ddbd-4468-ba2a-e52a39c9a4d5' User entered 'No (N)'	System	23 Sep 2020 23:36:40
	System	23 Sep 2020 23:36:40

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T18:36:33', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '0edad6e2-ddbd-4468-ba2a-e52a39c9a4d5' User entered 'No (N)'	System	23 Sep 2020 23:36:40
	System	23 Sep 2020 23:36:40

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T18:36:36', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '0edad6e2-ddbd-4468-ba2a-e52a39c9a4d5' User entered 'None (1)'	System	23 Sep 2020 23:36:40
	System	23 Sep 2020 23:36:40

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T18:36:38', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '0edad6e2-ddbd-4468-ba2a-e52a39c9a4d5' User entered '23 Sep 2020 18:36'	System	23 Sep 2020 23:36:40
	System	23 Sep 2020 23:36:40

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '23 Sep 2020 13:48'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	23 Sep 2020 15:01:39
User entered 'Day 2'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-24T18:37:12', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '2e38ff92-0305-4aa2-9ba1-959293bce38c' User entered 'None (1)'	System	24 Sep 2020 23:37:30
	System	24 Sep 2020 23:37:30

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-24T18:37:15', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '2e38ff92-0305-4aa2-9ba1-959293bce38c' User entered 'No (N)'	System	24 Sep 2020 23:37:30
	System	24 Sep 2020 23:37:30

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-24T18:37:17', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '2e38ff92-0305-4aa2-9ba1-959293bce38c' User entered 'No (N)'	System	24 Sep 2020 23:37:30
	System	24 Sep 2020 23:37:30

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-24T18:37:19', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '2e38ff92-0305-4aa2-9ba1-959293bce38c' User entered 'None (1)'	System	24 Sep 2020 23:37:30
	System	24 Sep 2020 23:37:30

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-24T18:37:24', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '2e38ff92-0305-4aa2-9ba1-959293bce38c' User entered '24 Sep 2020 18:37'	System	24 Sep 2020 23:37:30
	System	24 Sep 2020 23:37:30

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	23 Sep 2020 15:01:39
User entered 'Day 3'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-25T18:34:36', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '55807a47-1201-48a3-b9d7-162bcf545a90' User entered 'None (1)'	System	25 Sep 2020 23:34:47
	System	25 Sep 2020 23:34:47

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-25T18:34:39', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '55807a47-1201-48a3-b9d7-162bcf545a90' User entered 'No (N)'	System	25 Sep 2020 23:34:47
	System	25 Sep 2020 23:34:47

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-25T18:34:40', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '55807a47-1201-48a3-b9d7-162bcf545a90' User entered 'No (N)'	System	25 Sep 2020 23:34:47
	System	25 Sep 2020 23:34:47

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-25T18:34:42', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '55807a47-1201-48a3-b9d7-162bcf545a90' User entered 'None (1)'	System	25 Sep 2020 23:34:47
	System	25 Sep 2020 23:34:47

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-25T18:34:45', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '55807a47-1201-48a3-b9d7-162bcf545a90' User entered '25 Sep 2020 18:34'	System	25 Sep 2020 23:34:47
	System	25 Sep 2020 23:34:47

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	23 Sep 2020 15:01:39
User entered 'Day 4'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-26T18:50:25', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '483e35da-df06-4120-a4ed-ca0b490e3687'	System	26 Sep 2020 23:50:37
User entered 'None (1)'	System	26 Sep 2020 23:50:37

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-26T18:50:28', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '483e35da-df06-4120-a4ed-ca0b490e3687' User entered 'No (N)'	System	26 Sep 2020 23:50:37
	System	26 Sep 2020 23:50:37

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-26T18:50:30', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '483e35da-df06-4120-a4ed-ca0b490e3687' User entered 'No (N)'	System	26 Sep 2020 23:50:37
	System	26 Sep 2020 23:50:37

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-26T18:50:32', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '483e35da-df06-4120-a4ed-ca0b490e3687'	System	26 Sep 2020 23:50:37
User entered 'None (1)'	System	26 Sep 2020 23:50:37

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-26T18:50:34', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '483e35da-df06-4120-a4ed-ca0b490e3687' User entered '26 Sep 2020 18:50'	System	26 Sep 2020 23:50:37
	System	26 Sep 2020 23:50:37

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	23 Sep 2020 15:01:39
User entered 'Day 5'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-27T19:34:38', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'd4c871ec-1745-4e75-960c-ac7e84ac9eab' User entered 'None (1)'	System	28 Sep 2020 00:34:49
	System	28 Sep 2020 00:34:49

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-27T19:34:41', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'd4c871ec-1745-4e75-960c-ac7e84ac9eab' User entered 'No (N)'	System	28 Sep 2020 00:34:49
	System	28 Sep 2020 00:34:49

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-27T19:34:43', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'd4c871ec-1745-4e75-960c-ac7e84ac9eab' User entered 'No (N)'	System	28 Sep 2020 00:34:49
	System	28 Sep 2020 00:34:49

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-27T19:34:45', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'd4c871ec-1745-4e75-960c-ac7e84ac9eab' User entered 'None (1)'	System	28 Sep 2020 00:34:49
	System	28 Sep 2020 00:34:49

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-27T19:34:47', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'd4c871ec-1745-4e75-960c-ac7e84ac9eab' User entered '27 Sep 2020 19:34'	System	28 Sep 2020 00:34:49
	System	28 Sep 2020 00:34:49

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	23 Sep 2020 15:01:39
User entered 'Day 6'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-28T18:41:19', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'b1849dc8-a509-465b-8f93-49cd3a4529ab' User entered 'None (1)'	System	28 Sep 2020 23:41:31
	System	28 Sep 2020 23:41:31

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-28T18:41:21', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'b1849dc8-a509-465b-8f93-49cd3a4529ab' User entered 'No (N)'	System	28 Sep 2020 23:41:31
	System	28 Sep 2020 23:41:31

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-28T18:41:22', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'b1849dc8-a509-465b-8f93-49cd3a4529ab' User entered 'No (N)'	System	28 Sep 2020 23:41:31
	System	28 Sep 2020 23:41:31

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-28T18:41:24', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'b1849dc8-a509-465b-8f93-49cd3a4529ab' User entered 'None (1)'	System	28 Sep 2020 23:41:31
	System	28 Sep 2020 23:41:31

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-28T18:41:26', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'b1849dc8-a509-465b-8f93-49cd3a4529ab' User entered '28 Sep 2020 18:41'	System	28 Sep 2020 23:41:31
	System	28 Sep 2020 23:41:31

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	23 Sep 2020 15:01:39
User entered 'Day 7'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-29T18:09:40', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'c52192c5-3b1c-4e1f-8a75-bf32904bf1a4'	System	29 Sep 2020 23:10:08
User entered 'None (1)'	System	29 Sep 2020 23:10:08

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-29T18:09:42', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'c52192c5-3b1c-4e1f-8a75-bf32904bf1a4'	System	29 Sep 2020 23:10:08
User entered 'No (N)'	System	29 Sep 2020 23:10:08

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-29T18:09:44', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'c52192c5-3b1c-4e1f-8a75-bf32904bf1a4'	System	29 Sep 2020 23:10:08
User entered 'No (N)'	System	29 Sep 2020 23:10:08

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-29T18:09:45', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'c52192c5-3b1c-4e1f-8a75-bf32904bf1a4'	System	29 Sep 2020 23:10:08
User entered 'None (1)'	System	29 Sep 2020 23:10:08

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-29T18:09:47', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'c52192c5-3b1c-4e1f-8a75-bf32904bf1a4' User entered '29 Sep 2020 18:09'	System	29 Sep 2020 23:10:08
	System	29 Sep 2020 23:10:08

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	23 Sep 2020 15:01:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T10:37:33', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '183c29ee-03fc-4193-b11d-5a69df86d54a' User entered 'None (0)'	System	23 Sep 2020 15:38:01
	System	23 Sep 2020 15:38:01

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T10:37:36', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '183c29ee-03fc-4193-b11d-5a69df86d54a' User entered 'None (0)'	System	23 Sep 2020 15:38:01
	System	23 Sep 2020 15:38:01

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T10:37:40', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '183c29ee-03fc-4193-b11d-5a69df86d54a' User entered 'None (0)'	System	23 Sep 2020 15:38:01
	System	23 Sep 2020 15:38:01

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T10:37:45', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '183c29ee-03fc-4193-b11d-5a69df86d54a' User entered 'None (0)'	System	23 Sep 2020 15:38:01
	System	23 Sep 2020 15:38:01

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T10:37:49', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '183c29ee-03fc-4193-b11d-5a69df86d54a' User entered 'None (0)'	System	23 Sep 2020 15:38:01
	System	23 Sep 2020 15:38:01

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T10:37:52', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '183c29ee-03fc-4193-b11d-5a69df86d54a' User entered 'None (0)'	System	23 Sep 2020 15:38:01
	System	23 Sep 2020 15:38:01

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T10:37:56', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '183c29ee-03fc-4193-b11d-5a69df86d54a' User entered 'No (N)'	System	23 Sep 2020 15:38:01
	System	23 Sep 2020 15:38:01

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T10:37:59', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '183c29ee-03fc-4193-b11d-5a69df86d54a' User entered '23 Sep 2020 10:37'	System	23 Sep 2020 15:38:01
	System	23 Sep 2020 15:38:01

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '23 Sep 2020 10:23'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '23 Sep 2020 12:53'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	23 Sep 2020 15:01:39
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T18:36:42', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '01a096c2-8ac6-487b-b9eb-5791b87f7f5b' User entered 'None (0)'	System	23 Sep 2020 23:37:03
	System	23 Sep 2020 23:37:03

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T18:36:44', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '01a096c2-8ac6-487b-b9eb-5791b87f7f5b' User entered 'None (0)'	System	23 Sep 2020 23:37:03
	System	23 Sep 2020 23:37:03

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T18:36:47', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '01a096c2-8ac6-487b-b9eb-5791b87f7f5b' User entered 'None (0)'	System	23 Sep 2020 23:37:03
	System	23 Sep 2020 23:37:03

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T18:36:49', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '01a096c2-8ac6-487b-b9eb-5791b87f7f5b' User entered 'None (0)'	System	23 Sep 2020 23:37:03
	System	23 Sep 2020 23:37:03

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T18:36:50', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '01a096c2-8ac6-487b-b9eb-5791b87f7f5b' User entered 'None (0)'	System	23 Sep 2020 23:37:03
	System	23 Sep 2020 23:37:03

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T18:36:52', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '01a096c2-8ac6-487b-b9eb-5791b87f7f5b' User entered 'None (0)'	System	23 Sep 2020 23:37:03
	System	23 Sep 2020 23:37:03

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T18:36:58', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '01a096c2-8ac6-487b-b9eb-5791b87f7f5b' User entered 'No (N)'	System	23 Sep 2020 23:37:03
	System	23 Sep 2020 23:37:03

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-23T18:37:00', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '01a096c2-8ac6-487b-b9eb-5791b87f7f5b' User entered '23 Sep 2020 18:37'	System	23 Sep 2020 23:37:03
	System	23 Sep 2020 23:37:03

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '23 Sep 2020 13:48'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	23 Sep 2020 15:01:39
User entered 'Day 2'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-24T18:37:27', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '0b04a920-4a2c-4175-bc67-864412a3db38' User entered 'None (0)'	System	24 Sep 2020 23:37:43
	System	24 Sep 2020 23:37:43

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-24T18:37:28', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '0b04a920-4a2c-4175-bc67-864412a3db38' User entered 'None (0)'	System	24 Sep 2020 23:37:43
	System	24 Sep 2020 23:37:43

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-24T18:37:29', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '0b04a920-4a2c-4175-bc67-864412a3db38' User entered 'None (0)'	System	24 Sep 2020 23:37:43
	System	24 Sep 2020 23:37:43

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-24T18:37:31', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '0b04a920-4a2c-4175-bc67-864412a3db38' User entered 'None (0)'	System	24 Sep 2020 23:37:43
	System	24 Sep 2020 23:37:43

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-24T18:37:33', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '0b04a920-4a2c-4175-bc67-864412a3db38' User entered 'None (0)'	System	24 Sep 2020 23:37:43
	System	24 Sep 2020 23:37:43

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-24T18:37:34', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '0b04a920-4a2c-4175-bc67-864412a3db38' User entered 'None (0)'	System	24 Sep 2020 23:37:43
	System	24 Sep 2020 23:37:43

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-24T18:37:37', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '0b04a920-4a2c-4175-bc67-864412a3db38'	System	24 Sep 2020 23:37:43
User entered 'No (N)'	System	24 Sep 2020 23:37:43

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-24T18:37:39', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '0b04a920-4a2c-4175-bc67-864412a3db38' User entered '24 Sep 2020 18:37'	System	24 Sep 2020 23:37:43
	System	24 Sep 2020 23:37:43

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	23 Sep 2020 15:01:39
User entered 'Day 3'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-25T18:34:48', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '8d42810b-ac15-437d-81a9-db0dfe9b0ede' User entered 'None (0)'	System	25 Sep 2020 23:35:05
	System	25 Sep 2020 23:35:05

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-25T18:34:50', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '8d42810b-ac15-437d-81a9-db0dfe9b0ede' User entered 'None (0)'	System	25 Sep 2020 23:35:05
	System	25 Sep 2020 23:35:05

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-25T18:34:51', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '8d42810b-ac15-437d-81a9-db0dfe9b0ede' User entered 'None (0)'	System	25 Sep 2020 23:35:05
	System	25 Sep 2020 23:35:05

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-25T18:34:52', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '8d42810b-ac15-437d-81a9-db0dfe9b0ede' User entered 'None (0)'	System	25 Sep 2020 23:35:05
	System	25 Sep 2020 23:35:05

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-25T18:34:53', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '8d42810b-ac15-437d-81a9-db0dfe9b0ede' User entered 'None (0)'	System	25 Sep 2020 23:35:05
	System	25 Sep 2020 23:35:05

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-25T18:34:55', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '8d42810b-ac15-437d-81a9-db0dfe9b0ede' User entered 'None (0)'	System	25 Sep 2020 23:35:05
	System	25 Sep 2020 23:35:05

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-25T18:34:59', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '8d42810b-ac15-437d-81a9-db0dfe9b0ede' User entered 'No (N)'	System	25 Sep 2020 23:35:05
	System	25 Sep 2020 23:35:05

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-25T18:35:02', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '8d42810b-ac15-437d-81a9-db0dfe9b0ede' User entered '25 Sep 2020 18:35'	System	25 Sep 2020 23:35:05
	System	25 Sep 2020 23:35:05

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	23 Sep 2020 15:01:39
User entered 'Day 4'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-26T18:50:43', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'e47efbdc-ff16-400b-9e7a-bf8e35b054f4' User entered 'None (0)'	System	26 Sep 2020 23:51:00
	System	26 Sep 2020 23:51:00

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-26T18:50:44', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'e47efbdc-ff16-400b-9e7a-bf8e35b054f4' User entered 'None (0)'	System	26 Sep 2020 23:51:00
	System	26 Sep 2020 23:51:00

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-26T18:50:46', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'e47efbdc-ff16-400b-9e7a-bf8e35b054f4' User entered 'None (0)'	System	26 Sep 2020 23:51:00
	System	26 Sep 2020 23:51:00

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-26T18:50:47', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'e47efbdc-ff16-400b-9e7a-bf8e35b054f4' User entered 'None (0)'	System	26 Sep 2020 23:51:00
	System	26 Sep 2020 23:51:00

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-26T18:50:48', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'e47efbdc-ff16-400b-9e7a-bf8e35b054f4' User entered 'None (0)'	System	26 Sep 2020 23:51:00
	System	26 Sep 2020 23:51:00

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-26T18:50:51', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'e47efbdc-ff16-400b-9e7a-bf8e35b054f4' User entered 'None (0)'	System	26 Sep 2020 23:51:00
	System	26 Sep 2020 23:51:00

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-26T18:50:54', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'e47efbdc-ff16-400b-9e7a-bf8e35b054f4'	System	26 Sep 2020 23:51:00
User entered 'No (N)'	System	26 Sep 2020 23:51:00

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-26T18:50:56', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'e47efbdc-ff16-400b-9e7a-bf8e35b054f4' User entered '26 Sep 2020 18:50'	System	26 Sep 2020 23:51:00
	System	26 Sep 2020 23:51:00

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	23 Sep 2020 15:01:39
User entered 'Day 5'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-27T19:34:20', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'e5c25f3a-c11b-486f-a837-601eed3ae1fe' User entered 'None (0)'	System	28 Sep 2020 00:34:38
	System	28 Sep 2020 00:34:38

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-27T19:34:22', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'e5c25f3a-c11b-486f-a837-601eed3ae1fe' User entered 'None (0)'	System	28 Sep 2020 00:34:38
	System	28 Sep 2020 00:34:38

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-27T19:34:23', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'e5c25f3a-c11b-486f-a837-601eed3ae1fe' User entered 'None (0)'	System	28 Sep 2020 00:34:38
	System	28 Sep 2020 00:34:38

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-27T19:34:27', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'e5c25f3a-c11b-486f-a837-601eed3ae1fe' User entered 'None (0)'	System	28 Sep 2020 00:34:38
	System	28 Sep 2020 00:34:38

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-27T19:34:28', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'e5c25f3a-c11b-486f-a837-601eed3ae1fe' User entered 'None (0)'	System	28 Sep 2020 00:34:38
	System	28 Sep 2020 00:34:38

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-27T19:34:30', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'e5c25f3a-c11b-486f-a837-601eed3ae1fe' User entered 'None (0)'	System	28 Sep 2020 00:34:38
	System	28 Sep 2020 00:34:38

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-27T19:34:33', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'e5c25f3a-c11b-486f-a837-601eed3ae1fe' User entered 'No (N)'	System	28 Sep 2020 00:34:38
	System	28 Sep 2020 00:34:38

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-27T19:34:35', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'e5c25f3a-c11b-486f-a837-601eed3ae1fe' User entered '27 Sep 2020 19:34'	System	28 Sep 2020 00:34:38
	System	28 Sep 2020 00:34:38

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	23 Sep 2020 15:01:39
User entered 'Day 6'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-28T18:41:03', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '331e96c9-893c-464d-98be-c4e80a066c22' User entered 'None (0)'	System	28 Sep 2020 23:41:17
	System	28 Sep 2020 23:41:17

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-28T18:41:04', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '331e96c9-893c-464d-98be-c4e80a066c22' User entered 'None (0)'	System	28 Sep 2020 23:41:17
	System	28 Sep 2020 23:41:17

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-28T18:41:05', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '331e96c9-893c-464d-98be-c4e80a066c22' User entered 'None (0)'	System	28 Sep 2020 23:41:17
	System	28 Sep 2020 23:41:17

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-28T18:41:06', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '331e96c9-893c-464d-98be-c4e80a066c22' User entered 'None (0)'	System	28 Sep 2020 23:41:17
	System	28 Sep 2020 23:41:17

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-28T18:41:08', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '331e96c9-893c-464d-98be-c4e80a066c22' User entered 'None (0)'	System	28 Sep 2020 23:41:17
	System	28 Sep 2020 23:41:17

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-28T18:41:10', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '331e96c9-893c-464d-98be-c4e80a066c22' User entered 'None (0)'	System	28 Sep 2020 23:41:17
	System	28 Sep 2020 23:41:17

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-28T18:41:13', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '331e96c9-893c-464d-98be-c4e80a066c22'	System	28 Sep 2020 23:41:17
User entered 'No (N)'	System	28 Sep 2020 23:41:17

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-28T18:41:15', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '331e96c9-893c-464d-98be-c4e80a066c22' User entered '28 Sep 2020 18:41'	System	28 Sep 2020 23:41:17
	System	28 Sep 2020 23:41:17

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
Data entry locked.	System	23 Sep 2020 15:01:39
User entered 'Day 7'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-29T18:09:24', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'caf2179b-d8ea-45d7-9ee0-1913d1a359df' User entered 'None (0)'	System	29 Sep 2020 23:09:55
	System	29 Sep 2020 23:09:55

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-29T18:09:25', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'caf2179b-d8ea-45d7-9ee0-1913d1a359df' User entered 'None (0)'	System	29 Sep 2020 23:09:55
	System	29 Sep 2020 23:09:55

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-29T18:09:26', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'caf2179b-d8ea-45d7-9ee0-1913d1a359df' User entered 'None (0)'	System	29 Sep 2020 23:09:55
	System	29 Sep 2020 23:09:55

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-29T18:09:29', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'caf2179b-d8ea-45d7-9ee0-1913d1a359df' User entered 'None (0)'	System	29 Sep 2020 23:09:55
	System	29 Sep 2020 23:09:55

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-29T18:09:30', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'caf2179b-d8ea-45d7-9ee0-1913d1a359df' User entered 'None (0)'	System	29 Sep 2020 23:09:55
	System	29 Sep 2020 23:09:55

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-29T18:09:32', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'caf2179b-d8ea-45d7-9ee0-1913d1a359df' User entered 'None (0)'	System	29 Sep 2020 23:09:55
	System	29 Sep 2020 23:09:55

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:18

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 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-29T18:09:35', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'caf2179b-d8ea-45d7-9ee0-1913d1a359df' User entered 'No (N)'	System	29 Sep 2020 23:09:55
	System	29 Sep 2020 23:09:55

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-09-29T18:09:36', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'caf2179b-d8ea-45d7-9ee0-1913d1a359df' User entered '29 Sep 2020 18:09'	System	29 Sep 2020 23:09:55
	System	29 Sep 2020 23:09:55

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 15:01:39

US3572086

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:50:20
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 15:01:39

US3572086

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 17:57:26

US3572086

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '1 Oct 2020'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 17:57:26

US3572086

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 17:57:26

US3572086

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered empty.	(b) (4) (u) (4), (b) (6)	01 Oct 2020 17:57:26

US3572086

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	01 Oct 2020 17:57:35

US3572086

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'l'	System	01 Oct 2020 17:57:35

US3572086

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	07 Oct 2020 19:39:33

US3572086

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '7 Oct 2020'	(b) (4) (u) (4), (b) (6)	07 Oct 2020 19:39:33

US3572086

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (u) (4), (b) (6)	07 Oct 2020 19:39:33

US3572086

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered empty.	(b) (4) (u) (4), (b) (6)	07 Oct 2020 19:39:33

US3572086

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	07 Oct 2020 19:39:42

US3572086

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'l'	System	07 Oct 2020 19:39:42

US3572086

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	14 Oct 2020 21:06:38

US3572086

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '14 Oct 2020'	(b) (4) (u) (4), (b) (6)	14 Oct 2020 21:06:38

US3572086

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (u) (4), (b) (6)	14 Oct 2020 21:06:38

US3572086

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered empty.	(b) (4) (u) (4), (b) (6)	14 Oct 2020 21:06:38

US3572086

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22OCT2020 is reported under Visit 3 Day 57 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) (u) (4), (b) (6)	12 Feb 2021 07:16:33
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22OCT2020 is reported under Visit 3 Day 57 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.' answered with 'data added for V3D57' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 00:05:33
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22OCT2020 is reported under Visit 3 Day 57 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)	16 Nov 2020 14:27:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 21:06:44

US3572086

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'l'	System	14 Oct 2020 21:06:44

US3572086

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	10 Feb 2021 00:05:51

US3572086

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:18

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
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)	10 Feb 2021 00:06:25
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.'	System	10 Feb 2021 00:06:25
answered by data change (Site from System).		
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	10 Feb 2021 00:06:25
User entered '22 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 00:06:25
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	10 Feb 2021 00:05:51
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	10 Feb 2021 00:05:51
User entered '22 Oct 2021'	(b) (4), (b) (6)	10 Feb 2021 00:05:51

US3572086

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Clinic (Clinic)'	(b) (4) (u) (4), (b) (6)	10 Feb 2021 00:05:51

US3572086

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'VISIT3'	System	10 Feb 2021 00:05:51

US3572086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	10 Feb 2021 00:07:24

US3572086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '22 Oct 2020'	(b) (4) (u) (4), (b) (6)	10 Feb 2021 00:07:24

US3572086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '09:05'	(b) (4) (u) (4), (b) (6)	10 Feb 2021 00:07:24

US3572086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered '22 Oct 2020 09:05'	System	10 Feb 2021 00:07:24

US3572086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '97.5' F	(b) (4) (u) (4), (b) (6)	10 Feb 2021 00:07:24

US3572086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Other (Other)'	(b) (4) (u) (4), (b) (6)	10 Feb 2021 00:07:24

US3572086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Temporal'	(b) (4) (u) (4), (b) (6)	10 Feb 2021 00:07:24

US3572086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '75'	(b) (4) (u) (4), (b) (6)	10 Feb 2021 00:07:24

US3572086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'bpm'	System	10 Feb 2021 00:07:24

US3572086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '20'	(b) (4) (u) (4), (b) (6)	10 Feb 2021 00:07:24

US3572086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'breaths/min'	System	10 Feb 2021 00:07:24

US3572086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '153'	(b) (4) (u) (4), (b) (6)	10 Feb 2021 00:07:24

US3572086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'mmHg'	System	10 Feb 2021 00:07:24

US3572086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '81'	(b) (4) (u) (4), (b) (6)	10 Feb 2021 00:07:24

US3572086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'mmHg'	System	10 Feb 2021 00:07:24

US3572086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34

US3572086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:18

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34

US3572086

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	10 Feb 2021 00:07:38

US3572086

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '22 Oct 2020'	(b) (4) (u) (4), (b) (6)	10 Feb 2021 00:07:38

US3572086

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	10 Feb 2021 00:07:56

US3572086

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '22 Oct 2020'	(b) (4) (u) (4), (b) (6)	10 Feb 2021 00:07:56

US3572086

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered '09:20'	(b) (4) (u) (4), (b) (6)	10 Feb 2021 00:07:56

US3572086

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered '22 Oct 2020 09:20'	System	10 Feb 2021 00:07:56

US3572086

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	24 Feb 2021 04:23:14
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	16 Nov 2020 20:56:22

US3572086

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'I'	System	16 Nov 2020 20:56:22

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14
Data entry locked.	System	25 Aug 2020 16:30:49
User entered 'Day 64'	System	25 Aug 2020 16:30:49

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[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)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

Have you been exposed to someone with 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)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 08:18:18

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

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Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
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Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
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US3572086

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14
Data entry locked.	System	25 Aug 2020 16:30:49
User entered '25 Oct 2020 00:01'	System	25 Aug 2020 16:30:49

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14
Data entry locked.	System	25 Aug 2020 16:30:49
User entered '29 Oct 2020 23:59'	System	25 Aug 2020 16:30:49

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14
Data entry locked.	System	25 Aug 2020 16:30:49
User entered 'Day 71'	System	25 Aug 2020 16:30:49

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[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)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

Have you been exposed to someone with 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)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

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Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 08:18:18

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3572086

Folder: Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

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Folder: Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

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Folder: Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

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Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 08:18:18

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 08:18:18

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

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Folder: Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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Folder: Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
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[Date and time of submission](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14
Data entry locked.	System	25 Aug 2020 16:30:49
User entered '01 Nov 2020 00:01'	System	25 Aug 2020 16:30:49

US3572086

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14
Data entry locked.	System	25 Aug 2020 16:30:49
User entered '05 Nov 2020 23:59'	System	25 Aug 2020 16:30:49

US3572086

Folder: Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14
Data entry locked.	System	25 Aug 2020 16:30:49
User entered 'Day 78'	System	25 Aug 2020 16:30:49

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[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)
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Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

Have you been exposed to someone with 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)	24 Apr 2021 03:31:59
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Folder: Safety Follow Up Diary (1)

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[Please 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)
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US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

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Folder: Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14
Data entry locked.	System	25 Aug 2020 16:30:49
User entered '08 Nov 2020 00:01'	System	25 Aug 2020 16:30:49

US3572086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:31:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:24:14
Data entry locked.	System	25 Aug 2020 16:30:49
User entered '12 Nov 2020 23:59'	System	25 Aug 2020 16:30:49

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-11-21T18:45:34', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '7ea4a6db-b2a5-49e6-96f9-c432ea6c4cf9'	System	22 Nov 2020 01:00:18
User entered 'No (N)'	System	22 Nov 2020 01:00:18

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

Have you been exposed to someone with 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-11-21T19:00:06', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '7ea4a6db-b2a5-49e6-96f9-c432ea6c4cf9'	System	22 Nov 2020 01:00:18
User entered 'No (N)'	System	22 Nov 2020 01:00:18

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-11-21T19:00:15', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '7ea4a6db-b2a5-49e6-96f9-c432ea6c4cf9'	System	22 Nov 2020 01:00:18
User entered '21 Nov 2020 19:00:15'	System	22 Nov 2020 01:00:18

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-11-26T18:09:37', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'e7c21905-61f5-461b-ba27-68edc925240f'	System	27 Nov 2020 00:09:54
User entered 'No (N)'	System	27 Nov 2020 00:09:54

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

Have you been exposed to someone with 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-11-26T18:09:44', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'e7c21905-61f5-461b-ba27-68edc925240f'	System	27 Nov 2020 00:09:54
User entered 'No (N)'	System	27 Nov 2020 00:09:54

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-11-26T18:09:47', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'e7c21905-61f5-461b-ba27-68edc925240f' User entered '26 Nov 2020 18:09:47'	System	27 Nov 2020 00:09:54
	System	27 Nov 2020 00:09:54

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-12-03T18:58:53', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'a588e60e-197f-49fd-8116-55eed6f8688f' User entered 'No (N)'	System	04 Dec 2020 00:59:03
	System	04 Dec 2020 00:59:03

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

Have you been exposed to someone with 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-12-03T18:58:57', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'a588e60e-197f-49fd-8116-55eed6f8688f' User entered 'No (N)'	System	04 Dec 2020 00:59:03
	System	04 Dec 2020 00:59:03

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-12-03T18:59:00', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'a588e60e-197f-49fd-8116-55eed6f8688f' User entered '03 Dec 2020 18:59:00'	System	04 Dec 2020 00:59:03
	System	04 Dec 2020 00:59:03

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-12-10T18:23:48', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'acd4ddd3-9efa-4a3e-b258-cd256fe2b1fc'	System	11 Dec 2020 00:24:03
User entered 'No (N)'	System	11 Dec 2020 00:24:03

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

Have you been exposed to someone with 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-12-10T18:23:57', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'acd4ddd3-9efa-4a3e-b258-cd256fe2b1fc'	System	11 Dec 2020 00:24:03
User entered 'No (N)'	System	11 Dec 2020 00:24:03

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-12-10T18:24:00', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: 'acd4ddd3-9efa-4a3e-b258-cd256fe2b1fc'	System	11 Dec 2020 00:24:03
User entered '10 Dec 2020 18:24:00'	System	11 Dec 2020 00:24:03

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-12-17T18:42:10', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '3ec1e390-cb06-4850-a213-d7bc2cf0ac2c'	System	18 Dec 2020 00:42:20
User entered 'No (N)'	System	18 Dec 2020 00:42:20

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

Have you been exposed to someone with 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-12-17T18:42:16', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '3ec1e390-cb06-4850-a213-d7bc2cf0ac2c'	System	18 Dec 2020 00:42:20
User entered 'No (N)'	System	18 Dec 2020 00:42:20

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-12-17T18:42:18', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '3ec1e390-cb06-4850-a213-d7bc2cf0ac2c'	System	18 Dec 2020 00:42:20
User entered '17 Dec 2020 18:42:18'	System	18 Dec 2020 00:42:20

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-12-25T19:19:09', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '7161d86d-5001-4931-8c83-0962f5f1f771'	System	26 Dec 2020 01:19:21
User entered 'No (N)'	System	26 Dec 2020 01:19:21

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

Have you been exposed to someone with 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-12-25T19:19:14', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '7161d86d-5001-4931-8c83-0962f5f1f771'	System	26 Dec 2020 01:19:21
User entered 'No (N)'	System	26 Dec 2020 01:19:21

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-12-25T19:19:17', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '7161d86d-5001-4931-8c83-0962f5f1f771' User entered '25 Dec 2020 19:19:17'	System	26 Dec 2020 01:19:21
	System	26 Dec 2020 01:19:21

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-12-31T18:51:52', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '25a63ed9-179f-45fd-a5d1-edc18752a2db'	System	01 Jan 2021 00:52:04
User entered 'No (N)'	System	01 Jan 2021 00:52:04

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

Have you been exposed to someone with 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-12-31T18:51:55', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '25a63ed9-179f-45fd-a5d1-edc18752a2db'	System	01 Jan 2021 00:52:04
User entered 'No (N)'	System	01 Jan 2021 00:52:04

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2F86B47-D698-4AEC-83C1-1E6C385D5B27)', Time: '2020-12-31T18:51:58', User OID: 'PatientReportedOutcome (US3572086)', ODM File OID: '25a63ed9-179f-45fd-a5d1-edc18752a2db' User entered '31 Dec 2020 18:51:58'	System	01 Jan 2021 00:52:04
	System	01 Jan 2021 00:52:04

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

Have you been exposed to someone with 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Please 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Please 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Please 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

Have you been exposed to someone with 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

Please 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Please 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Please 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

Have you been exposed to someone with 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Please 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Please 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Please 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

Have you been exposed to someone with 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Please 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Please 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Please 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Have you been exposed to someone with 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Please 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Please 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

Please 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

Have you been exposed to someone with 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

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[Please 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Body aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Sore throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Runny nose](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Please 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Please 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 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 02:24:14

US3572086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:45:47
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:24:14
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 02:24:14

US3572086

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:13:12
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	16 Nov 2020 20:57:43

US3572086

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:13:12
User entered '16 Nov 2020'	(b) (4) (u) (4), (b) (6)	16 Nov 2020 20:57:43

US3572086

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:13:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (u) (4), (b) (6)	16 Nov 2020 20:57:43

US3572086

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:13:12
User entered empty.	(b) (4) (u) (4), (b) (6)	16 Nov 2020 20:57:43

US3572086

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:13:12
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	16 Nov 2020 20:57:52

US3572086

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:52:34
User entered 'l'	System	16 Nov 2020 20:57:52

US3572086

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:09:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	22 Dec 2020 17:37:22

US3572086

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:09:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered '22 Dec 2020'	(b) (4) (u) (4), (b) (6)	22 Dec 2020 17:37:22

US3572086

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:09:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (u) (4), (b) (6)	22 Dec 2020 17:37:22

US3572086

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:09:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered empty.	(b) (4) (u) (4), (b) (6)	22 Dec 2020 17:37:22

US3572086

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:09:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	22 Dec 2020 17:37:26

US3572086

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:09:26
User entered 'l'	System	22 Dec 2020 17:37:26

US3572086

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:09:26
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:46
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	24 Feb 2021 17:34:22

US3572086

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:09:26
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:46
User entered '19 Jan 2021'	(b) (4) (u) (4), (b) (6)	24 Feb 2021 17:34:22

US3572086

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:09:26
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (u) (4), (b) (6)	24 Feb 2021 17:34:22

US3572086

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:09:26
User closed query 'Per DM CLR RQ: Response noted. However the AE of positive COVID-19 recorded on AE Log is not within the timeframe of this safety call. Please review and update data, else clarify.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 09:05:33
Query 'Per DM CLR RQ: Response noted. However the AE of positive COVID-19 recorded on AE Log is not within the timeframe of this safety call. Please review and update data, else clarify.' answered with 'AE has been updated' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 17:20:09
User opened query 'Per DM CLR RQ: Response noted. However the AE of positive COVID-19 recorded on AE Log is not within the timeframe of this safety call. Please review and update data, else clarify.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 05:38:48
User closed query 'Per DM CLR: Review specified comment, HE TESTED (+) FOR COVID 19.. Verify if this condition meets AE reporting criteria per protocol 8.3.6. If yes, update AE page as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 05:38:48
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:46
Query 'Per DM CLR: Review specified comment, HE TESTED (+) FOR COVID 19.. Verify if this condition meets AE reporting criteria per protocol 8.3.6. If yes, update AE page as appropriate. Else, provide clarification. ' answered with 'AE of positive COVID-19 results is recorded on AE Log' (Site from DM).	(b) (4) (u) (4), (b) (6)	12 Apr 2021 22:01:31
User opened query 'Per DM CLR: Review specified comment, HE TESTED (+) FOR COVID 19.. Verify if this condition meets AE reporting criteria per protocol 8.3.6. If yes, update AE page as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 08:46:17
User entered 'Subject at nursing home due to stroke. He tested (+) for COVID 19.'	(b) (4), (b) (6)	24 Feb 2021 17:34:22

US3572086

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:09:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	24 Feb 2021 17:34:27

US3572086

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:09:26
User entered 'l'	System	24 Feb 2021 17:34:27

US3572086

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:09:26
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
Signature has been broken.	(b) (4) (u) (4), (b) (6)	21 Apr 2021 21:26:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 21:26:03
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 20:58:23

US3572086

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:09:26
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (u) (4), (b) (6)	23 Apr 2021 10:02:17
User closed query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	21 Apr 2021 21:26:03
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	21 Apr 2021 21:26:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 21:26:03
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'call OOW due site making multiple attempts to call; subject had died however site was not notified until 25MAR by next of kin' (Site from System).	(b) (4), (b) (6)	21 Apr 2021 05:03:04
User opened query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	21 Apr 2021 05:01:21
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	21 Apr 2021 05:01:21
User closed query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	21 Apr 2021 05:01:21

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Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	21 Apr 2021 05:01:21
User entered '24 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 05:01:21
User opened query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	21 Apr 2021 04:56:10
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	21 Apr 2021 04:56:10
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	21 Apr 2021 04:56:10
User closed query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	21 Apr 2021 04:56:10
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	21 Apr 2021 04:56:10
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 04:56:10
User entered '19 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 04:56:10
User opened query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	20 Apr 2021 14:36:46
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	20 Apr 2021 14:36:46
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:25:34

PRODUCTION RELEASE (v12.003
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Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 14:36:13
User entered '17 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 20:58:23

US3572086

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:09:26
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
Signature has been broken.	(b) (4) (u) (4), (b) (6)	21 Apr 2021 21:26:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 21:26:03
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 20:58:23

US3572086

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:09:26
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
User entered empty; reason for change Data Entry Error	(b) (4) (u) (4), (b) (6)	21 Apr 2021 21:26:03
User entered 'CALL ATTEMPTED BUT NOT REACHED DUE TO Death of subject; notified by niece of death' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 05:01:21
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 04:56:10
User entered 'Call attempted but not reached due to subject being hospitalized' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 04:56:10
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered '3 ATTEMPTS DAILY TO CONTACT SUBJECT from feb 17 through feb 26. NO VM SET UP. TEXT MESSAGE SENT. EMERGENCY CONTACT # SEEMS TO BE DISABLED. CLINIC SITE NOTIFIED.' reason for change: Data Entry Error	(b) (4) (u) (4), (b) (6)	26 Feb 2021 20:58:44
User entered '3 attempts daily to contact subject. No vm set up. Text message sent. Emergency contact # seems to be disabled. Clinic site notified.'	(b) (4), (b) (6)	26 Feb 2021 20:58:23

US3572086

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:09:26
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	09 Mar 2021 16:17:50

US3572086

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:09:26
User entered 'l'	System	09 Mar 2021 16:17:50

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:18:18

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:47:08
User entered '13 Jan 2021'	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:02:04

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Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:18:18

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
DataPoint Verified.	(u) (4), (b) (6)	26 Apr 2021 11:03:56
	(b) (4), (b) (6)	23 Apr 2021 17:47:08
Query 'Data is required. Please complete.' answered with 'unk' (Site from System).	Maria Candelario (b) (4)	23 Apr 2021 09:02:16
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 09:02:04
User entered empty.	Maria Candelario (b) (4)	23 Apr 2021 09:02:04
	(b) (4)	

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Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:18:18

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered empty.	System	23 Apr 2021 09:02:04

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:18:18

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:47:08
User entered 'Convalescent Tele-visit (Convalescent Tele-visit)'	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:02:04

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:18:18

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:47:08
User entered 'Yes (Y)'	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:02:04

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
User entered 'Day 1 (Day 1)'	(b) (4) Maria Candelario (b) (4)	23 Apr 2021 09:02:54

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered '03 Jan 2021' reason for change: Data Entry Error	Maria Candelario (b) (4)	23 Apr 2021 09:04:25
User entered '13 Jan 2021'	(b) (4) Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:02:54

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered '1' reason for change: Data Entry Error	Maria Candelario (b) (4)	23 Apr 2021 10:19:00
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:02:54

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:02:54

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered empty.	System	23 Apr 2021 09:02:54

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:02:54

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:02:54

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:02:54

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:02:54

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:02:54

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:02:54

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:02:54

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:02:54

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:02:54

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:02:54

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:02:54

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:02:54

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:02:54

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:02:54

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:02:54

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:02:54

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:18:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:02:54

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
User entered 'Day 2 (Day 2)'	(b) (4) Maria Candelario (b) (4)	23 Apr 2021 09:03:32

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4)	
	(u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered '04 Jan 2021' reason for change: Data Entry Error	Maria Candelario (b) (4)	23 Apr 2021 09:04:25
User entered '14 Jan 2021'	(b) (4)	
	Maria Candelario (b) (4)	23 Apr 2021 09:03:32
	(b) (4)	

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered '1' reason for change: Data Entry Error	Maria Candelario (b) (4)	23 Apr 2021 10:19:00
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:03:32

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:03:32

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered empty.	System	23 Apr 2021 09:03:32

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:03:32

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:03:32

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:03:32

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:03:32

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:03:32

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:03:32

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:03:32

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:03:32

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:03:32

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:03:32

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:03:32

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:03:32

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:03:32

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:03:32

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:03:32

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:03:32

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:18:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:03:32

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
User entered 'Day 3 (Day 3)'	(b) (4) Maria Candelario (b) (4)	23 Apr 2021 09:04:25

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered '05 Jan 2021'	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:04:25

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered '1' reason for change: Data Entry Error	Maria Candelario (b) (4)	23 Apr 2021 10:19:00
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:04:25

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:04:25

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered empty.	System	23 Apr 2021 09:04:25

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:04:25

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:04:25

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:04:25

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:04:25

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:04:25

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:04:25

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:04:25

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:04:25

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:04:25

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:04:25

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:04:25

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:04:25

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:04:25

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:04:25

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:04:25

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:04:25

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:18:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:04:25

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
User entered 'Day 4 (Day 4)'	(b) (4) Maria Candelario (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered '6 Jan 2021'	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered '1' reason for change: Data Entry Error	Maria Candelario (b) (4)	23 Apr 2021 10:19:00
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered empty.	System	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:18:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
User entered 'Day 5 (Day 5)'	(b) (4) Maria Candelario (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 09:08:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Apr 2021 09:08:00
User entered '7 Jan 2021' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:08:00
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 09:05:59
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered '1' reason for change: Data Entry Error	Maria Candelario (b) (4)	23 Apr 2021 10:19:00
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered empty.	System	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:18:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
User entered 'Day 6 (Day 6)'	(b) (4) Maria Candelario (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 09:08:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Apr 2021 09:08:00
User entered '8 Jan 2021' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:08:00
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 09:05:59
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered '1' reason for change: Data Entry Error	Maria Candelario (b) (4)	23 Apr 2021 10:19:00
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered empty.	System	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:18:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
User entered 'Day 7 (Day 7)'	(b) (4) Maria Candelario (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 09:08:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Apr 2021 09:08:00
User entered '9 Jan 2021' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:08:00
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 09:05:59
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered '1' reason for change: Data Entry Error	Maria Candelario (b) (4)	23 Apr 2021 10:19:00
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered empty.	System	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:18:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
User entered 'Day 8 (Day 8)'	(b) (4) Maria Candelario (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 09:08:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Apr 2021 09:08:00
User entered '10 Jan 2021' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:08:00
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 09:05:59
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered '1' reason for change: Data Entry Error	Maria Candelario (b) (4)	23 Apr 2021 10:19:00
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered empty.	System	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:18:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
User entered 'Day 9 (Day 9)'	(b) (4) Maria Candelario (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 09:08:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Apr 2021 09:08:00
User entered '11 Jan 2021' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:08:00
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 09:05:59
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered '1' reason for change: Data Entry Error	Maria Candelario (b) (4)	23 Apr 2021 10:19:00
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered empty.	System	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:18:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:18:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
User entered 'Day 10 (Day 10)'	(b) (4) Maria Candelario (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:18:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 09:08:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Apr 2021 09:08:00
User entered '12 Apr 2021' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:08:00
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 09:05:59
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:18:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4)	
	(u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered '1' reason for change: Data Entry Error	Maria Candelario (b) (4)	23 Apr 2021 10:19:00
User entered '0'	(b) (4)	
	Maria Candelario (b) (4)	23 Apr 2021 09:05:59
	(b) (4)	

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:18:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:18:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered empty.	System	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:18:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:18:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:18:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:18:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:18:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:18:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:18:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:18:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:18:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:18:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:18:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:18:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:18:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:18:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:18:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:18:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:18:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:05:59

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:18:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
User entered 'Day 11 (Day 11)'	(b) (4) Maria Candelario (b) (4)	23 Apr 2021 09:08:00

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:18:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered '13 Jan 2021'	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:08:00

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:18:18

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered '1' reason for change: Data Entry Error	Maria Candelario (b) (4)	23 Apr 2021 10:19:00
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:08:00

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:18:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:08:00

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:18:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered empty.	System	23 Apr 2021 09:08:00

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:18:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:08:00

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:18:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:08:00

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:18:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:08:00

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:18:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:08:00

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:18:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:08:00

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:18:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:08:00

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:18:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:08:00

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:18:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:08:00

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:18:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:08:00

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:18:18

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:08:00

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:18:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:08:00

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:18:18

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:08:00

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:18:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:08:00

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:18:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:08:00

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:18:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:08:00

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:18:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:08:00

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:18:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 22:07:08
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:08:00

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:18:18

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:45:54
User entered '3 Jan 2021'	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:46:26

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:18:18

[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 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:45:54
User entered 'Yes (Y)'	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:46:26

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:18:18

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 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4) (u) (4), (b) (6)	26 Apr 2021 11:02:49
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:45:54
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'test was positive' (Site from System).	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:46:44
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	23 Apr 2021 09:46:26
User entered 'Yes (Y)'	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:46:26

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Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:18:18

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:45:54
User entered '3 Jan 2021'	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:46:26

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Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:18:18

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:45:54
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:46:26

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:18:18

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:45:54
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:46:26

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Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:18:18

[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 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:45:54
User entered 'Yes (Y)'	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:46:26

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Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:18:18

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:45:54
User entered 'Laredo medical center'	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:46:26

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:18:18

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:45:54
User entered 'Yes (Y)'	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 09:46:26

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:18:18

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered 'l'	System	23 Apr 2021 09:46:26

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:18:18

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered 'No (N)'	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:18:18

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:18:18

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:18:18

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:18:18

Did the subject have Heart Rate $\geq$ 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered 'No (N)'	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:18:18

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:18:18

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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Form: Covid-19 Severity Assessment

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:18:18

Did the subject have Oxygen Saturation of SpO2 $\leq$ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered 'No (N)'	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:18:18

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:18:18

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:18:18

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:18:18

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered 'No (N)'	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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Folder: Covid-19 Assessment 13 Jan 2021

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:18:18

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered 'No (N)'	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:18:18

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:18:18

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 10:15:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Apr 2021 10:15:23
User entered 'No (N)' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:23
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 10:15:10
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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Folder: Covid-19 Assessment 13 Jan 2021

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:18:18

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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Folder: Covid-19 Assessment 13 Jan 2021

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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[End Date](#)

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Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:18:18

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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[Start Date](#)

Audit	User	Time (GMT)
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DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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Audit	User	Time (GMT)
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User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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Audit	User	Time (GMT)
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User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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Audit	User	Time (GMT)
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DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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Generated On: 10 Jun 2021 08:18:18

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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Folder: Covid-19 Assessment 13 Jan 2021

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

US3572086

Folder: Covid-19 Assessment 13 Jan 2021

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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
Query 'per EMR/medical records from hospitalization /discharge summary, Subject was diagnosed with Pneumonia due to COVID infection. Please verify and provide answer to this question accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 17:44:41
User opened query 'per EMR/medical records from hospitalization /discharge summary, Subject was diagnosed with Pneumonia due to COVID infection. Please verify and provide answer to this question accordingly.' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 17:19:26
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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Folder: Covid-19 Assessment 13 Jan 2021

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 08:18:18

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
Query 'per EMR/medical records from hospitalization , CT scan showed evidence of pneumonia. Please verify and provide resposne to this question accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 17:44:43
User opened query 'per EMR/medical records from hospitalization , CT scan showed evidence of pneumonia. Please verify and provide resposne to this question accordingly.' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 17:09:03
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

US3572086

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[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered 'No (N)'	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

US3572086

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

US3572086

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:44:51
User entered empty.	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:15:10

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:18:18

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	23 Apr 2021 17:19:58
User entered 'No (N)'	Maria Candelario (b) (4) (b) (4)	23 Apr 2021 10:16:00

US3572086

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

Form: Visit Date

Generated On: 10 Jun 2021 08:18:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4)	26 Mar 2021 18:09:02

US3572086

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

Form: Visit Date

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered empty.	(b) (4) Maria Candelario (b) (4)	26 Mar 2021 18:09:02

US3572086

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

Form: Visit Date

Generated On: 10 Jun 2021 08:18:18

[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 17:19:09
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered empty.	(b) (4) Maria Candelario (b) (4)	26 Mar 2021 18:09:02

US3572086

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

Form: Visit Date

Generated On: 10 Jun 2021 08:18:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered 'UNBLND_DECIDE'	System	26 Mar 2021 18:09:02

US3572086

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

Form: Unblinding

Generated On: 10 Jun 2021 08:18:18

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:53
User closed query 'Per CDM: 'NA unblinded under A5 and study discontinued' is not ticked and consent date is blank. Please review as one of these fields should be completed.' (Site from DM).	(b) (4) (u) (4), (b) (6)	15 Apr 2021 15:04:40
Query 'Per CDM: 'NA unblinded under A5 and study discontinued' is not ticked and consent date is blank. Please review as one of these fields should be completed.' answered with 'updated' (Site from DM).	Caitlin roll (b) (4)	13 Apr 2021 15:31:10
Signature has been broken.	Caitlin roll (b) (4)	13 Apr 2021 15:30:53
User entered '25 Aug 2020' reason for change: Data Entry Error	Caitlin roll (b) (4)	13 Apr 2021 15:30:53
User opened query 'Per CDM: 'NA unblinded under A5 and study discontinued' is not ticked and consent date is blank. Please review as one of these fields should be completed.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 07:21:24
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered empty.	(b) (4) (u) (4), (b) (6)	01 Apr 2021 17:10:52

US3572086

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

Form: Unblinding

Generated On: 10 Jun 2021 08:18:18

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered '0'	(b) (4) (u) (4), (b) (6)	01 Apr 2021 17:10:52

US3572086

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

Form: Unblinding

Generated On: 10 Jun 2021 08:18:18

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	01 Apr 2021 17:10:52

US3572086

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

Form: Unblinding

Generated On: 10 Jun 2021 08:18:18

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:46
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' (Site from DM).	(b) (4) (u) (4), (b) (6)	12 Apr 2021 09:32:25
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' answered with 'updated' (Site from DM).	Caitlin roll (b) (4)	08 Apr 2021 19:00:33
Signature has been broken.	Caitlin roll (b) (4)	08 Apr 2021 19:00:06
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	Caitlin roll (b) (4)	08 Apr 2021 19:00:06
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 12:55:13
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered 'Amendment 5 (Amendment 5)'	(b) (4) (u) (4), (b) (6)	01 Apr 2021 17:10:52

US3572086

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

Form: Unblinding

Generated On: 10 Jun 2021 08:18:18

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered '30 Mar 2021'	(b) (4) (u) (4), (b) (6)	01 Apr 2021 17:10:52

US3572086

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

Form: Unblinding

Generated On: 10 Jun 2021 08:18:18

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered 'Placebo (Placebo)'	(b) (4) (u) (4), (b) (6)	01 Apr 2021 17:10:52

US3572086

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

Form: Unblinding

Generated On: 10 Jun 2021 08:18:18

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered 'Placebo (Placebo)'	(b) (4) (u) (4), (b) (6)	01 Apr 2021 17:10:52

US3572086

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

Form: Unblinding

Generated On: 10 Jun 2021 08:18:18

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered 'Placebo (Placebo)'	(b) (4) (u) (4), (b) (6)	01 Apr 2021 17:10:52

US3572086

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

Form: Unblinding

Generated On: 10 Jun 2021 08:18:18

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	01 Apr 2021 17:10:52

US3572086

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

Form: Unblinding

Generated On: 10 Jun 2021 08:18:18

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered 'I'	System	01 Apr 2021 17:10:52

US3572086

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

Form: Unblinding

Generated On: 10 Jun 2021 08:18:18

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered empty.	System	01 Apr 2021 17:10:52

US3572086

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	01 Apr 2021 17:10:56

US3572086

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered empty.	(b) (4) (u) (4), (b) (6)	01 Apr 2021 17:10:56

US3572086

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered empty.	(b) (4) (u) (4), (b) (6)	01 Apr 2021 17:10:56

US3572086

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered empty.	System	01 Apr 2021 17:10:56

US3572086

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:18:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	01 Apr 2021 17:10:59

US3572086

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:18:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered empty.	(b) (4) (u) (4), (b) (6)	01 Apr 2021 17:10:59

US3572086

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:18:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered empty.	(b) (4) (u) (4), (b) (6)	01 Apr 2021 17:10:59

US3572086

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered empty.	System	01 Apr 2021 17:10:59

US3572086

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:18:18

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User closed query 'Per CDM: Subject can no longer participate in study due to death from COVID 19 as entered on the AE log. Please ensure End of Study/ Study discontinuation form is completed as required and reason for discontinuation is specified. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 07:02:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:59
Query 'Per CDM: Subject can no longer participate in study due to death from COVID 19 as entered on the AE log. Please ensure End of Study/ Study discontinuation form is completed as required and reason for discontinuation is specified. ' answered with 'Study discontinuation form is completed and reason (death) is specified. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 15:22:46
User opened query 'Per CDM: Subject can no longer participate in study due to death from COVID 19 as entered on the AE log. Please ensure End of Study/ Study discontinuation form is completed as required and reason for discontinuation is specified. ' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 19:30:13
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User closed query 'Per CDM: "Did participant experience any adverse event" recorded as "No" however, adverse events are recorded on corresponding page. Please review and update accordingly. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	09 Mar 2021 04:15:51
Query 'Per CDM: "Did participant experience any adverse event" recorded as "No" however, adverse events are recorded on corresponding page. Please review and update accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 05:34:37
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 05:34:30

US3572086

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:18:18

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: "Did participant experience any adverse event" recorded as "No" however, adverse events are recorded on corresponding page. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 05:11:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 17:34:50
User closed query 'Per CDM: "Did participant experience any adverse event" recorded "No" however adverse events recorded corresponding page. Please review and update accordingly. else clarify ' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 09:48:20
Query 'Per CDM: "Did participant experience any adverse event" recorded "No" however adverse event recorded corresponding page. Please review and update accordingly. else clarify ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 03:09:38
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Jan 2021 03:09:27
User opened query 'Per CDM: "Did participant experience any adverse event" recorded "No" however adverse events recorded corresponding page. Please review and update accordingly. else clarify ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:10:11
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:58:00
User closed query 'Per CDM: "Did participant experience any adverse event" recorded "No" however adverse events recorded corresponding page. Please review and update accordingly. else clarify' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 05:57:32
Query 'Per CDM: "Did participant experience any adverse event" recorded "No" however adverse event recorded corresponding page. Please review and update accordingly. else clarify' answered with 'updated' (Site from DM).	Alisha Lutat (b) (4) (b) (4)	23 Oct 2020 03:44:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Alisha Lutat (b) (4) (b) (4)	23 Oct 2020 03:44:15

US3572086

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:18:18

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: "Did participant experience any adverse event" recorded "No" however adverse events recorded corresponding page. Please review and update accordingly. else clarify' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 10:07:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 21:07:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 14:58:46
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 17:58:17

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'Per MM: If this is a prolonged event, please update the term to a medical diagnosis such as hypertension.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 10:01:05
User closed query 'Per DM CLR: Please confirm if this AE is a worsening of the same condition noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure that grade is greater than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria.	(b) (4), (b) (6)	17 Feb 2021 17:56:44
' (Site from DM).		
Query 'Per MM: If this is a prolonged event, please update the term to a medical diagnosis such as hypertension.	(b) (4), (b) (6)	16 Feb 2021 18:53:23
' answered with 'It appears that subject's baseline blood pressure was 157/85 and subject has a history of hypertension. On Month1, subject's blood pressure was 152/82. Blood pressure was in the 150s/80s during other visits.' (Site from DM).		
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\23.0.	Coder Import (b) (4)	16 Feb 2021 18:52:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Feb 2021 18:52:00
Data point term sent to Coder	System	16 Feb 2021 18:51:21
Coding entries removed.	(b) (4), (b) (6)	16 Feb 2021 18:50:45
User entered 'Worsening of hypertension' reason for change: Per Query Resolution	(b) (4), (b) (6)	16 Feb 2021 18:50:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please confirm if this AE is a worsening of the same condition noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure that grade is greater than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' answered with 'It appears that subject's baseline blood pressure was 157/85 and subject has a history of hypertension. On Month1, subject's blood pressure was 152/82. Blood pressure was in the 150s/80s during other visits.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 18:48:09
User opened query 'Per MM: If this is a prolonged event, please update the term to a medical diagnosis such as hypertension. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 05:30:54
User opened query 'Per DM CLR: Please confirm if this AE is a worsening of the same condition noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure that grade is greater than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 12:14:46
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Vascular tests NEC (incl blood pressure), PT: Blood pressure increased, LLT: Increased blood pressure - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 15:06:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 15:06:31
Data point term sent to Coder	System	14 Oct 2020 15:05:24
User entered 'ELEVATED BLOOD PRESSURE'	(b) (4), (b) (6)	14 Oct 2020 15:04:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	14 Oct 2020 15:04:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	14 Oct 2020 15:04:31

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	14 Oct 2020 15:04:31

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '23 Sep 2020'	(b) (4) (u) (4), (b) (6)	14 Oct 2020 15:04:31

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '09:00'	(b) (4) (u) (4), (b) (6)	14 Oct 2020 15:04:31

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
User entered '23 Sep 2020 09:00'	System	14 Oct 2020 15:04:31

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'Per DM CLR RQ: Response noted. Please review and update the status of this AE when data is available. Thank you.' (Site from DM).	(b) (4)	
Query 'Per DM CLR RQ: Response noted. Please review and update the status of this AE when data is available. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 06:59:41
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	05 Apr 2021 03:30:07
User entered 'No (N)' reason for change: Data Entry Error	System	05 Apr 2021 03:29:53
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	05 Apr 2021 03:29:53
User opened query 'Per DM CLR RQ: Response noted. Please review and update the status of this AE when data is available. Thank you.' (Site from DM).	System	02 Apr 2021 16:10:01
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.	(b) (4), (b) (6)	22 Mar 2021 03:21:33
' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 03:21:33
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.	Maria Candelario (b) (4)	19 Mar 2021 14:22:30
' answered with 'pending medical record' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.	(b) (4), (b) (6)	17 Mar 2021 08:20:42
' (Site from DM).		
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 15:04:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) System	05 Apr 2021 03:29:53
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	05 Apr 2021 03:29:53
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	02 Apr 2021 16:10:01
User entered '12 Feb 2021' reason for change: New Information	(b) (4), (b) (6)	02 Apr 2021 16:10:01
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 15:04:31

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered with 'time unknown' (Site from System).	(b) (4), (b) (6)	06 Apr 2021 06:59:54
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 03:30:55
User entered empty.	System	05 Apr 2021 03:29:53
	(b) (4), (b) (6)	14 Oct 2020 15:04:31

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
User entered empty.	System	14 Oct 2020 15:04:31

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 04:42:15
Query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 03:55:18
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 03:55:11
User opened query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 08:45:03
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	14 Oct 2020 15:04:31

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	14 Oct 2020 15:04:31

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0'	(b) (4) (u) (4), (b) (6)	14 Oct 2020 15:04:31

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0'	(b) (4) (u) (4), (b) (6)	14 Oct 2020 15:04:31

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0'	(b) (4) (u) (4), (b) (6)	14 Oct 2020 15:04:31

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) (u) (4), (b) (6)	14 Oct 2020 15:04:31

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) (u) (4), (b) (6)	14 Oct 2020 15:04:31

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) (u) (4), (b) (6)	14 Oct 2020 15:04:31

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) (u) (4), (b) (6)	14 Oct 2020 15:04:31

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0'	(b) (4) (u) (4), (b) (6)	14 Oct 2020 15:04:31

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0'	(b) (4) (u) (4), (b) (6)	14 Oct 2020 15:04:31

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0'	(b) (4) (u) (4), (b) (6)	14 Oct 2020 15:04:31

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'Not Related (NOT RELATED)'	(b) (4) (u) (4), (b) (6)	14 Oct 2020 15:04:31

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'Not Related (NOT RELATED)'	(b) (4) (u) (4), (b) (6)	14 Oct 2020 15:04:31

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'None (NONE)'	(b) (4) (u) (4), (b) (6)	14 Oct 2020 15:04:31

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	14 Oct 2020 15:05:58
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 15:05:58
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	14 Oct 2020 15:04:31
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 15:04:31

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0'	(b) (4) (u) (4), (b) (6)	14 Oct 2020 15:04:31

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0'	(b) (4) (u) (4), (b) (6)	14 Oct 2020 15:04:31

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 03:29:53
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 15:05:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 15:05:58
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 15:05:58
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 15:04:31
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 15:04:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) (u) (4), (b) (6)	14 Oct 2020 15:04:31

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) (u) (4), (b) (6)	14 Oct 2020 15:04:31

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
User entered '0'	System	14 Oct 2020 15:04:31

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39
User entered '0'	System	14 Oct 2020 15:04:31

US3572086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:39

US3572086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:34:23
User entered 'USA-US091-2021-mRNA-1273-P301000001'	System	20 Jan 2021 15:30:31
User entered 'New'	(b) (4), (b) (6)	20 Jan 2021 15:30:31

US3572086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'PV Query: Please update the event term to just the specific disease when medical information is provided.' (Site from Safety).	(b) (4)	
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: CVA - version MedDRA\23.0.	(b) (4), (b) (6)	03 Feb 2021 20:13:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Feb 2021 23:51:43
Data point term sent to Coder	(b) (4)	
Query 'PV Query: Please update the event term to just the specific disease when medical information is provided.' answered with 'updated' (Site from Safety).	System	02 Feb 2021 23:50:43
Coding entries removed.	(b) (4), (b) (6)	02 Feb 2021 23:50:00
User entered 'CVA' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Feb 2021 23:49:48
User opened query 'PV Query: Please update the event term to just the specific disease when medical information is provided.' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 23:49:48
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Stroke - version MedDRA\23.0.	(b) (4), (b) (6)	29 Jan 2021 16:38:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	26 Jan 2021 21:13:54
Data point term sent to Coder	(b) (4)	
User entered 'Subject reported hospitalization for Stroke, pending medical records'	System	26 Jan 2021 21:13:54
	(b) (4), (b) (6)	19 Jan 2021 20:34:26
		19 Jan 2021 20:33:54

US3572086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	19 Jan 2021 20:33:54

US3572086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	19 Jan 2021 20:33:54

US3572086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	19 Jan 2021 20:33:54

US3572086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'PV Query: Subject had neurological signs of stroke 3 days before admission. Please confirm if onset date should be updated.' (Site from Safety).	(b) (4)	
Query 'PV Query: Subject had neurological signs of stroke 3 days before admission. Please confirm if onset date should be updated.' answered with 'updated ' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 14:44:01
Query 'PV Query: Subject had neurological signs of stroke 3 days before admission. Please confirm if onset date should be updated.' answered with 'updated ' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 18:39:46
User entered '31 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 18:39:36
User opened query 'PV Query: Subject had neurological signs of stroke 3 days before admission. Please confirm if onset date should be updated.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 04:31:32
User entered '03 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Feb 2021 23:49:48
User entered '1 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 20:33:54

US3572086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) (u) (4), (b) (6)	19 Jan 2021 20:33:54

US3572086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered empty.	System	19 Jan 2021 20:33:54

US3572086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	(u) (4), (b) (6)	02 Feb 2021 23:49:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 20:33:54

US3572086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	30 Apr 2021 16:37:40
User closed query 'PV Query: Event end date for CVA was reported as 03 Jan 2021, but subject was not discharged until 13 Jan 2021. Please confirm if end date should be updated. If not, please clarify. ' (Site from Safety).	(b) (4)	30 Apr 2021 15:32:46
DataPoint Verified.	(u) (4), (b) (6)	
	(b) (4), (b) (6)	30 Apr 2021 03:16:19
Query 'PV Query: Event end date for CVA was reported as 03 Jan 2021, but subject was not discharged until 13 Jan 2021. Please confirm if end date should be updated. If not, please clarify. ' answered with 'date has been updated' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 20:04:30
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 20:04:03
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 20:04:03
User entered '13 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 20:04:03
User opened query 'PV Query: Event end date for CVA was reported as 03 Jan 2021, but subject was not discharged until 13 Jan 2021. Please confirm if end date should be updated. If not, please clarify. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:21:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '3 Jan 2021' reason for change: Data Entry Error	(b) (4)	
User entered empty.	(u) (4), (b) (6)	02 Feb 2021 23:49:48
	(b) (4), (b) (6)	19 Jan 2021 20:33:54

US3572086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) (u) (4), (b) (6)	19 Jan 2021 20:33:54

US3572086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:21:07
Query 'PV Query: Event end date for CVA was reported as 03 Jan 2021, but subject was not discharged until 13 Jan 2021. Please confirm if end date should be updated. If not, please clarify.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:21:04
User opened query 'PV Query: Event end date for CVA was reported as 03 Jan 2021, but subject was not discharged until 13 Jan 2021. Please confirm if end date should be updated. If not, please clarify.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 04:31:47
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 16:39:26
User entered empty.	System	19 Jan 2021 20:33:54

US3572086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'PV Query: Please provide event severity.' (Site from Safety).	(b) (4)	
Query 'PV Query: Please provide event severity.' answered with 'Data updated' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 16:42:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	09 Feb 2021 15:25:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 15:23:31
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	System	09 Feb 2021 15:23:31
User opened query 'PV Query: Please provide event severity.' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 15:23:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	29 Jan 2021 16:38:37
User entered empty.	System	19 Jan 2021 20:33:54
	(b) (4), (b) (6)	19 Jan 2021 20:33:54

US3572086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	19 Jan 2021 20:33:54

US3572086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0'	(b) (4) (u) (4), (b) (6)	19 Jan 2021 20:33:54

US3572086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0'	(b) (4) (u) (4), (b) (6)	19 Jan 2021 20:33:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4)	03 Feb 2021 20:13:26
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'data submitted via fax' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 00:11:40
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		02 Feb 2021 23:49:48
Query 'Requires inpatient or prolongation of existing System Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		02 Feb 2021 23:49:48
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 16:39:11
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	19 Jan 2021 20:33:54

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EAB) (1725)

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Folder: Adverse Events

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	19 Jan 2021 20:33:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '3 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	(u) (4), (b) (6)	02 Feb 2021 23:49:48
User entered '1 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 20:33:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 20:13:30
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'data submitted via fax' (Site from Safety).	(b) (4), (b) (6)	03 Feb 2021 00:11:27
User entered '13 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Feb 2021 23:49:48
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 16:39:17
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 20:33:54

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	19 Jan 2021 20:33:54

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) (u) (4), (b) (6)	19 Jan 2021 20:33:54

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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0'	(b) (4) (u) (4), (b) (6)	19 Jan 2021 20:33:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0'	(b) (4) (u) (4), (b) (6)	19 Jan 2021 20:33:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0'	(b) (4) (u) (4), (b) (6)	19 Jan 2021 20:33:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible. ' (Site from Safety).	(b) (4)	
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible. ' answered with 'Data updated as per PI' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 19:37:57
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible. ' answered with 'Data updated as per PI' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 17:58:00
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 17:44:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Jan 2021 17:44:38
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 17:44:38
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)	20 Jan 2021 15:38:15
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 20:33:54
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 20:33:54

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Form: Adverse Events (2)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	21 Jan 2021 17:44:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Jan 2021 17:44:38
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 17:44:38
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 20:33:54
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 20:33:54

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Folder: Adverse Events

Form: Adverse Events (2)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (u) (4), (b) (6)	19 Jan 2021 20:33:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0' reason for change: Data Entry Error	(b) (4) (u) (4), (b) (6)	03 Mar 2021 07:24:02
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	10 Feb 2021 19:08:29
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 19:08:29
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Jan 2021 20:33:54
User entered '0'	(b) (4), (b) (6)	19 Jan 2021 20:33:54

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Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Mar 2021 07:24:02
User entered '0'	(b) (4), (b) (6)	19 Jan 2021 20:33:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0'	(b) (4) (u) (4), (b) (6)	19 Jan 2021 20:33:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'PV Query: Please provide the event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4)	
Query 'PV Query: Please provide the event outcome, when available. Please keep query open until resolution is achieved.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 16:42:48
Query 'PV Query: Please provide the event outcome, when available. Please keep query open until resolution is achieved.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 00:32:39
User closed query 'Per CDM: Please close the query once the Outcome is updated.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 02:52:33
Query 'Per CDM: Please close the query once the Outcome is updated.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 00:12:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	03 Feb 2021 00:11:02
Data Entry Error		
User opened query 'PV Query: Please provide the event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 16:39:41
User opened query 'Per CDM: Please close the query once the Outcome is updated.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 08:00:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	25 Jan 2021 07:58:31
Query 'Data is required. Please complete.' answered with 'recovering, the subject was transfer to a nursing home. pending additional records' (Site from System).	(b) (4), (b) (6)	21 Jan 2021 18:01:09
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 20:33:54
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 20:33:54

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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 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) (u) (4), (b) (6)	19 Jan 2021 20:33:54

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'Per DM CLR: Narrative indicates that the subject was given O2 supplement, REMDESIVIR and CONVALESCENT PLASMA. However, there are no recorded Concomitant Medications that match the information. Please update to record the corresponding ConMeds as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 02:16:27
Query 'Per DM CLR: Narrative indicates that the subject was given O2 supplement, REMDESIVIR and CONVALESCENT PLASMA. However, there are no recorded Concomitant Medications that match the information. Please update to record the corresponding ConMeds as appropriate. Otherwise, clarify.' answered with 'Data updated' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 14:58:18
User opened query 'Per DM CLR: Narrative indicates that the subject was given O2 supplement, REMDESIVIR and CONVALESCENT PLASMA. However, there are no recorded Concomitant Medications that match the information. Please update to record the corresponding ConMeds as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 13:41:03
User closed query 'Per DM CLR RQ: Response noted. However please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate when data is available.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 08:49:06
Query 'Per DM CLR RQ: Response noted. However please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate when data is available.' answered with 'Confirmed this should be more than one AE, all AEs captured in AE eCRF. Data updated.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 03:04:18

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR RQ: Response noted. However please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate when data is available.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 03:25:02
User closed query 'Per DM CLR: Narrative = PATIENT WAS FOUND TO BE COVID 19 POSITIVE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 03:25:02
Query 'Per DM CLR: Narrative = PATIENT WAS FOUND TO BE COVID 19 POSITIVE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'pending medical record' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 14:23:26
User closed query 'Per DM CLR: Narrative = PATIENT RECEIVED REMDESIVIR FOR 5 DAYS AND CONVALESCENT PLASMA FOR COVID19. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 03:51:54
User closed query 'Per DM CLR: Narrative = REHAB FOR ONGOING PT/OT. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 03:51:33
User closed query 'Per DM CLR: Narrative = CONVALESCENT PLASMA FOR COVID19. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 03:50:37
User closed query 'Per DM CLR: Narrative = INCENTIVE SPIROMETRY WAS ORDERED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 03:50:23

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Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = O2 SUPPLEMENT WAS PROVIDED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 03:50:05
Query 'Per DM CLR: Narrative = REHAB FOR ONGOING PT/OT. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Already on the Con-Procedure log. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 15:55:11
Query 'Per DM CLR: Narrative = PATIENT RECEIVED REMDESIVIR FOR 5 DAYS AND CONVALESCENT PLASMA FOR COVID19. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Both were added to the Con-Procedure log.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 15:54:46
Query 'Per DM CLR: Narrative = INCENTIVE SPIROMETRY WAS ORDERED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Added. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 15:54:20
Query 'Per DM CLR: Narrative = O2 SUPPLEMENT WAS PROVIDED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Added.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 15:48:36
Query 'Per DM CLR: Narrative = CONVALESCENT PLASMA FOR COVID19. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'ADDED' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 15:11:48
User opened query 'Per DM CLR: Narrative = CONVALESCENT PLASMA FOR COVID19. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 08:48:26

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = PATIENT WAS FOUND TO BE COVID 19 POSITIVE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 08:48:02
User closed query 'Per DM CLR: Narrative = HYPERLIPIDEMIA. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 09:30:47
User closed query 'Per DM CLR: Narrative = FALL. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 04:31:43
Query 'Per DM CLR: Narrative = HYPERLIPIDEMIA. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'HYPERLIPIDEMIA ADDED AS MH.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 23:45:14
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 14:33:42
Query 'Per DM CLR: Narrative = FALL. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'per source fall not noted as ae' (Site from DM).	Caitlin roll (b) (4)	01 Mar 2021 18:57:37

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Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with ' Patient received Remdesivir for 5 days and convalescent plasma for Covid19' (Site from Safety).	Caitlin roll (b) (4)	01 Mar 2021 18:56:49
User closed query 'PV Query: It was reported that the subject tested positive for COVID-19 during hospitalization. Please confirm if this was considered a symptomatic positive case of COVID-19. If yes, please add this event to the eCRF and provide all COVID-19 assessment forms in the eCRF, as applicable. If the subject was confirmed asymptomatic please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 15:01:49
User closed query 'PV Query: Please confirm date of CT of head.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 15:01:45
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)	01 Mar 2021 15:01:38
Query 'PV Query: It was reported that the subject tested positive for COVID-19 during hospitalization. Please confirm if this was considered a symptomatic positive case of COVID-19. If yes, please add this event to the eCRF and provide all COVID-19 assessment forms in the eCRF, as applicable. If the subject was confirmed asymptomatic please state so.' answered with 'the subject was Asymptomatic ' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 18:08:06
Query 'PV Query: Please confirm date of CT of head.' answered with '03jan2021' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 06:22:17
Query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc.)' answered with 'unclear ' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 06:12:29
User opened query 'Per DM CLR: Narrative = REHAB FOR ONGOING PT/OT. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 11:26:53

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = PATIENT RECEIVED REMDESIVIR FOR 5 DAYS AND CONVALESCENT PLASMA FOR COVID19. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 11:26:47
User opened query 'Per DM CLR: Narrative = INCENTIVE SPIROMETRY WAS ORDERED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 11:26:38
User opened query 'Per DM CLR: Narrative = O2 SUPPLEMENT WAS PROVIDED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 11:26:32
User opened query 'Per DM CLR: Narrative = HYPERLIPIDEMIA. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 11:26:26
User opened query 'Per DM CLR: Narrative = FALL. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 11:26:21
User opened query 'PV Query: It was reported that the subject tested positive for COVID-19 during hospitalization. Please confirm if this was considered a symptomatic positive case of COVID-19. If yes, please add this event to the eCRF and provide all COVID-19 assessment forms in the eCRF, as applicable. If the subject was confirmed asymptomatic please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 04:33:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for CVA event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 04:33:07
User opened query 'PV Query: Please provide treatment given for CVA event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 04:32:50
User opened query 'PV Query: Please confirm date of CT of head.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 04:32:03
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)	19 Feb 2021 04:30:27
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 16:42:45
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 16:42:43

US3572086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'lab results submitted as per query request on 08Jan2021' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 00:32:18
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'PCR positive at the hospital' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 00:23:21
User entered 'The subject presented to the hospital with headache, neck pain, upper back pain, and Pelvic pain status post fall onset Dec 25, 2020. Patient denied LOC and is presenting facial drooping to right side of face. The subject with past medical history of stroke, hypertension and hyperlipidemia. Was admitted for presenting Neurological signs of stroke that have been present for 3 days before admission. Patient was convinced by his care taker to come to the hospital. After being assessed in the ED, patient was found to be Covid 19 positive. Patient was admitted to the Covid unit for supportive therapy and Neurology was consulted. During hospitalization patient remained hemodynamically stable, stated weakness and mild SOB for which O2 supplement was provided with alleviation of symptoms. Suspicion for some deconditioning was made, incentive spirometry was ordered. Patient received Remdesivir for 5 days and convalescent plasma for Covid19. Patient was deemed for discharge to Laredo nursing and rehab for ongoing PT/OT. Patient will continue current treatment at this moment and will benefit from rehabilitation.' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Feb 2021 23:49:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 16:39:49
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 16:39:34
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 16:39:02
User entered 'Subject called to inform the site he was hospitalized. pending medical records'	(b) (4), (b) (6)	19 Jan 2021 20:33:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered 'I'	System	19 Jan 2021 20:33:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered '0'	System	19 Jan 2021 20:33:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered '0'	System	19 Jan 2021 20:33:54

US3572086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 14:34:23
Un-reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 13:08:16
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 13:08:16
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 16:43:41
User entered 'USA-US091-2021-mRNA-1273-P301000001'	(b) (4), (b) (6)	10 Feb 2021 16:43:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'Per MM: Please confirm if the subject was evaluated for COVID-19. (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 03:12:01
User closed query 'Per MM: Please confirm this AE does not meet the definition of an SAE once the data is available.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 03:11:55
Query 'Per MM: Please confirm this AE does not meet the definition of an SAE once the data is available.' answered with 'Yes' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 14:57:08
Query 'Per MM: Please confirm if the subject was evaluated for COVID-19. answered with 'Yes' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 14:56:59
User opened query 'Per MM: Please confirm if the subject was evaluated for COVID-19. (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 05:27:42
User opened query 'Per MM: Please confirm this AE does not meet the definition of an SAE once the data is available.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 03:05:08
User closed query 'Per MM: Please confirm this AE does not meet the definition of an SAE' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 03:05:08
Query 'Per MM: Please confirm this AE does not meet the definition of an SAE' answered with 'Already Recorded SAE for CVA, pending medical records' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 14:26:46
User opened query 'Per MM: Please confirm this AE does not meet the definition of an SAE' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 11:31:58
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\23.0.	Coder Import (b) (4)	11 Feb 2021 21:00:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Feb 2021 21:00:56
Data point term sent to Coder	System	11 Feb 2021 20:45:31

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'PNEUMONIA' reason for change:	(b) (4), (b) (6)	11 Feb 2021 20:44:34
Data Entry Error		
Data point term sent to Coder	System	09 Feb 2021 22:11:25
Coding entries removed.	(b) (4), (b) (6)	09 Feb 2021 22:10:44
User entered 'PNEUMONIA Due to COVID' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 22:10:44
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Feb 2021 17:08:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Feb 2021 17:08:33
Data point term sent to Coder	System	09 Feb 2021 17:08:15
User entered 'Pneumonia'	(b) (4), (b) (6)	09 Feb 2021 17:07:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	09 Feb 2021 17:07:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	09 Feb 2021 17:07:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'PV Query Urgent: Is this an event of positive symptomatic Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:57:02
Query 'PV Query Urgent: Is this an event of positive symptomatic Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' answered with 'Spoke with (b) (6) from Quvia, The subject had no symptoms. Discharge Summary will be fax to 1-866-599-1342' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 20:44:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 20:42:32
User opened query 'PV Query Urgent: Is this an event of positive symptomatic Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 13:07:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 17:07:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '3 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	(u) (4), (b) (6)	09 Feb 2021 21:50:58
User entered '3 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 17:07:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Feb 2021 17:07:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
User entered empty.	System	09 Feb 2021 17:07:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	09 Feb 2021 17:07:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) System	10 Feb 2021 00:17:46
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	10 Feb 2021 00:17:46
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	10 Feb 2021 00:17:15
User closed query 'End date is prior to Start date. Please correct.' (Site from System).	System	09 Feb 2021 21:50:58
User opened query 'End date is prior to Start date. Please correct.' (Site from System).	System	09 Feb 2021 17:07:15
User entered '13 Jan 2021'	(b) (4), (b) (6)	09 Feb 2021 17:07:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Feb 2021 17:07:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
User entered empty.	System	09 Feb 2021 17:07:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (u) (4), (b) (6)	09 Feb 2021 17:07:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
Query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide seriousness criteria as soon as possible. ' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:57:05
User opened query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide seriousness criteria as soon as possible. ' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 13:07:58
User entered 'No (N)'	(b) (4), (b) (6)	09 Feb 2021 17:07:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0'	(b) (4) (u) (4), (b) (6)	09 Feb 2021 17:07:15

US3572086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0'	(b) (4) (u) (4), (b) (6)	09 Feb 2021 17:07:15

US3572086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0'	(b) (4) (u) (4), (b) (6)	09 Feb 2021 17:07:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Feb 2021 17:07:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Feb 2021 17:07:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Feb 2021 17:07:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Feb 2021 17:07:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0'	(b) (4) (u) (4), (b) (6)	09 Feb 2021 17:07:15

US3572086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0'	(b) (4) (u) (4), (b) (6)	09 Feb 2021 17:07:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0'	(b) (4) (u) (4), (b) (6)	09 Feb 2021 17:07:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Feb 2021 00:16:48
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	10 Feb 2021 00:16:48
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	10 Feb 2021 00:16:48
User entered empty.	System	09 Feb 2021 17:07:15
	(b) (4), (b) (6)	09 Feb 2021 17:07:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	10 Feb 2021 00:16:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Feb 2021 00:16:48
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 00:16:48
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 17:07:15
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 17:07:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	10 Feb 2021 00:16:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Feb 2021 00:16:48
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 00:16:48
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 17:07:15
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 17:07:15

US3572086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User closed query 'Per CDM: Response says updated. However there is no Con Med updated for this Adverse event. Please review and update data accordingly. Otherwise clarify.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	12 Apr 2021 11:01:36
	Milton Haber (b) (4)	11 Apr 2021 07:07:07
Query 'Per CDM: Response says updated. However there is no Con Med updated for this Adverse event. Please review and update data accordingly. Otherwise clarify.' answered with 'The patient has passed away so unable to call and confirm if there was a Con Med taken. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	08 Apr 2021 14:23:57
User opened query 'Per CDM: Response says updated. However there is no Con Med updated for this Adverse event. Please review and update data accordingly. Otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 02:24:04
User closed query 'Per MM: Response noted. However once data is available, please review and confirm if treatment was given and if so, update "other action taken", and CM page, as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 02:17:33
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	06 Apr 2021 14:57:47
Query 'Per MM: Response noted. However once data is available, please review and confirm if treatment was given and if so, update "other action taken", and CM page, as appropriate. ' answered with 'Data updated' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 14:57:39
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	06 Apr 2021 14:57:27
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 14:57:27

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

None

Audit	User	Time (GMT)
User opened query 'Per MM: Response noted. However once data is available, please review and confirm if treatment was given and if so, update "other action taken", and CM page, as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 03:27:45
User closed query 'Per MM: Please review and confirm if treatment was given and if so, update "other action taken", and CM page, as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 03:27:45
Query 'Per MM: Please review and confirm if treatment was given and if so, update "other action taken", and CM page, as appropriate.' answered with 'pending medical record' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 14:26:59
User opened query 'Per MM: Please review and confirm if treatment was given and if so, update "other action taken", and CM page, as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 11:35:01
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	10 Feb 2021 00:17:15
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 00:17:15
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Feb 2021 17:07:15
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 17:07:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '1' reason for change: Data Entry Error	(b) (4) (u) (4), (b) (6)	06 Apr 2021 14:57:47
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 17:07:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0'	(b) (4) (u) (4), (b) (6)	09 Feb 2021 17:07:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4)	
	(u) (4), (b) (6)	10 Feb 2021 00:17:46
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 00:17:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Feb 2021 00:17:15
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 00:17:15
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 17:07:15
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 17:07:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Feb 2021 17:07:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Feb 2021 17:07:15

US3572086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
User entered '0'	System	09 Feb 2021 17:07:15

US3572086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43
User entered 'I'	System	09 Feb 2021 17:07:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:18:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:00
User entered 'USA-US091-2021-mRNA-1273-P301000015'	System	26 Mar 2021 22:46:52
User entered 'New'	(b) (4), (b) (6)	26 Mar 2021 22:46:52

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
Query 'COVID AE is entered but no COVID folders are completed. Please enter COVID Contact, Diagnostic and severity assessment. Severity information to be entered based on hospital records.' canceled (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 17:47:47
User opened query 'COVID AE is entered but no COVID folders are completed. Please enter COVID Contact, Diagnostic and severity assessment. Severity information to be entered based on hospital records.' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 22:37:32
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	(b) (4), (b) (6)	11 Apr 2021 07:07:07
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	25 Mar 2021 20:34:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Mar 2021 20:34:30
Data point term sent to Coder	System	25 Mar 2021 20:34:04
User entered 'Covid-19'	(b) (4), (b) (6)	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'PV URGENT Query: Event term is COVID-19, please consider updating this field to Yes. Else clarify. ' (Site from Safety).	(b) (4)	
Query 'PV URGENT Query: Event term is COVID-19, please consider updating this field to Yes. Else clarify. ' answered with 'Data updated' (Site from Safety).	(b) (4), (b) (6)	27 Mar 2021 00:49:15
Query 'PV URGENT Query: Event term is COVID-19, please consider updating this field to Yes. Else clarify. ' answered with 'Data updated' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 18:31:11
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 18:11:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Mar 2021 18:11:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 18:11:02
User opened query 'PV URGENT Query: Event term is COVID-19, please consider updating this field to Yes. Else clarify. ' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 14:00:49
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 20:33:45
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:53
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 17:19:51
User entered '3 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 17:19:51
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 18:11:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Mar 2021 18:11:02
User entered '8 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 18:11:02
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 20:33:45
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) (u) (4), (b) (6)	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered empty.	System	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'PV URGENT Query: Please update field with the full date of onset.' (Site from Safety).	(b) (4)	
	(b) (4), (b) (6)	27 Mar 2021 00:49:18
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Mar 2021 18:32:40
User entered '12 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 18:32:40
Query 'PV URGENT Query: Please update field with the full date of onset.' answered with 'Data updated' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 18:31:18
User opened query 'PV URGENT Query: Please update field with the full date of onset.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 14:08:58
Query 'PV URGERNT Query: Please update field with the full date of onset.' canceled (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 14:08:05
User opened query 'PV URGERNT Query: Please update field with the full date of onset.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 14:02:00
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	25 Mar 2021 20:33:45
User entered '12 Feb ' (non-conformant).	(b) (4), (b) (6)	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) (u) (4), (b) (6)	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered empty.	System	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	26 Mar 2021 18:32:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Mar 2021 18:32:13
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 18:32:13
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 20:33:45
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'l'	(b) (4) (u) (4), (b) (6)	25 Mar 2021 20:33:45

US3572086

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0'	(b) (4) (u) (4), (b) (6)	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
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)	27 Mar 2021 03:10:44
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	27 Mar 2021 03:10:44
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Mar 2021 03:10:44
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	25 Mar 2021 20:33:45
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '23 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	(u) (4), (b) (6)	06 Apr 2021 14:33:18
User entered '08 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Mar 2021 03:10:44
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'Per CDM: Hospital discharge date is prior to Hospital admission date. Please update the Hospital Discharge Date appropriately' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 02:19:34
Query 'Per CDM: Hospital discharge date is prior to Hospital admission date. Please update the Hospital Discharge Date appropriately' answered with 'Data has been corrected' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 14:33:55
User entered '12 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 14:17:25
User opened query 'Per CDM: Hospital discharge date is prior to Hospital admission date. Please update the Hospital Discharge Date appropriately' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 06:35:23
User closed query 'Hospital discharge date is prior to Hospital admission date. Please correct. □' (Site from System).	(b) (4), (b) (6)	30 Mar 2021 10:28:47
Query 'Hospital discharge date is prior to Hospital admission date. Please correct. □' answered with 'updated' (Site from System).	(b) (4), (b) (6)	27 Mar 2021 03:10:51
User opened query 'Hospital discharge date is prior to System Hospital admission date. Please correct. □' (Site from System).		27 Mar 2021 03:10:44
User entered '12 Feb 2012' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Mar 2021 03:10:44
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'Per CDM RQ: Response Noted. However, Admitted to ICU? is Unknown. Please leave this query open until the response can be updated to Yes or No' (Site from DM).	(b) (4)	
Query 'Per CDM RQ: Response Noted. However, Admitted to ICU? is Unknown. Please leave this query open until the response can be updated to Yes or No' answered with 'Data updated' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 02:19:44
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 14:47:01
User opened query 'Per CDM RQ: Response Noted. However, Admitted to ICU? is Unknown. Please leave this query open until the response can be updated to Yes or No' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 14:46:47
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)	30 Mar 2021 03:06:05
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 'pending ' (Site from System).	(b) (4), (b) (6)	30 Mar 2021 03:05:09
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).	(b) (4), (b) (6)	27 Mar 2021 03:11:29
User entered 'Unknown (UNK)'	System	25 Mar 2021 20:33:45
	(b) (4), (b) (6)	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) (u) (4), (b) (6)	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0'	(b) (4) (u) (4), (b) (6)	25 Mar 2021 20:33:45

US3572086

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0'	(b) (4) (u) (4), (b) (6)	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0'	(b) (4) (u) (4), (b) (6)	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'PV URGENT Query: Please update field to Related/Not Related, as applicable.' (Site from Safety).	(b) (4)	
Query 'PV URGENT Query: Please update field to Related/Not Related, as applicable.' answered with 'updated ' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 16:29:39
Query 'PV URGENT Query: Please update field to Related/Not Related, as applicable.' answered with 'updated ' (Site from Safety).	(b) (4), (b) (6)	27 Mar 2021 03:11:05
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Mar 2021 03:10:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Mar 2021 03:10:44
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Mar 2021 03:10:44
User opened query 'PV URGENT Query: Please update field to Related/Not Related, as applicable.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 14:03:30
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 20:33:45
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'PV URGENT Query: Please update field to Related/Not Related, as applicable.' (Site from Safety).	(b) (4)	
Query 'PV URGENT Query: Please update field to Related/Not Related, as applicable.' answered with 'updated ' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 16:29:43
Query 'PV URGENT Query: Please update field to Related/Not Related, as applicable.' answered with 'updated ' (Site from Safety).	(b) (4), (b) (6)	27 Mar 2021 03:11:10
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Mar 2021 03:10:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Mar 2021 03:10:44
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Mar 2021 03:10:44
User opened query 'PV URGENT Query: Please update field to Related/Not Related, as applicable.' (Site from Safety).	(b) (4), (b) (6)	27 Mar 2021 00:42:51
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 20:33:45
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (u) (4), (b) (6)	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4) (b) (4)	11 Apr 2021 07:07:07
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	06 Apr 2021 14:47:46
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 14:47:46
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	06 Apr 2021 14:47:33
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	27 Mar 2021 03:10:44
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Mar 2021 03:10:44
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	25 Mar 2021 20:33:45
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '1' reason for change: Data Entry Error	(b) (4) (u) (4), (b) (6)	06 Apr 2021 14:47:33
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0'	(b) (4) (u) (4), (b) (6)	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'Fatal (FATAL)'	(b) (4) (u) (4), (b) (6)	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

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 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) (u) (4), (b) (6)	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 23:15:08
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
User closed query 'PV Query: Please confirm cause of death to be COVID-19. Subject tested negative for COVID-19 and respiratory viral panel was negative. Subject met criteria for sepsis and subject began treatment for CVA with enoxaparin on same date as event start date.' (Site from Safety).	(b) (4)	
Query 'PV Query: Please confirm cause of death to be COVID-19. Subject tested negative for COVID-19 and respiratory viral panel was negative. Subject met criteria for sepsis and subject began treatment for CVA with enoxaparin on same date as event start date.' answered with 'updated' (Site from Safety).	(u) (4), (b) (6)	26 Apr 2021 17:06:43
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 20:02:51
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 20:02:42
User entered '@1407(REPORT OF DEATH) THE SITE RECEIVED A CALL FROM THE SUBJECTS NIECE TO INFORM US, SUBJECT HAS PASSED AWAY ON 12FEB2021.' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 20:02:42
User opened query 'PV Query: Please confirm cause of death to be COVID-19. Subject tested negative for COVID-19 and respiratory viral panel was negative. Subject met criteria for sepsis and subject began treatment for CVA with enoxaparin on same date as event start date.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 14:40:48
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:23
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with subject's death.' (Site from Safety).	(b) (4)	
	(u) (4), (b) (6)	07 Apr 2021 17:01:29

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide events leading to subject's death, (hospitalized, found at home... ect.)' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 16:58:02
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 16:57:59
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)	07 Apr 2021 16:53:44
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 16:53:13
User closed query 'PV Query: Subject was reported to have due to COVID-19. Please provide symptoms of COVID-19 as applicable.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 16:53:11
User closed query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 16:53:04
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Data updated in Con Meds' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 14:56:23
Query 'PV Query: Subject was reported to have due to COVID-19. Please provide symptoms of COVID-19 as applicable.' answered with 'Discharged summary faxed' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 14:42:22

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with subject's death.' answered with 'Discharged summary faxed' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 14:41:51
Query 'PV Query: Please provide events leading to subject's death, (hospitalized, found at home... ect.)' answered with 'Discharged summary Faxed' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 14:41:37
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Redacted Discharged Summary faxed' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 14:41:02
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 'No Autopsy performed' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 14:40:08
Query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' answered with 'NO' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 14:32:39
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with subject's death.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 01:31:20
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 01:31:09
User opened query 'PV Query: Please provide events leading to subject's death, (hospitalized, found at home... ect.)' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 01:30:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

[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.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 01:30:41
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 01:30:22
User opened query 'PV Query: Subject was reported to have due to COVID-19. Please provide symptoms of COVID-19 as applicable.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 01:30:08
User opened query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 01:29:53
User entered '@1407(Report of Death) the site received a call from the subjects Niece to inform us, subject has passed away due to COVID on 12Feb2021.'	(b) (4), (b) (6)	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered 'I'	System	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered 'I'	System	25 Mar 2021 20:33:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered '0'	System	25 Mar 2021 20:33:45

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:18:18

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	(b) (4), (b) (6)	03 Apr 2021 04:25:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Alisha Lutat (b) (4) (b) (4)	23 Mar 2021 15:47:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 17:34:57
User closed query 'Per CDM: It was mentioned for "Were any prior/concomitant medications and/or vaccinations taken?" as "No". However, Concomitant medications were captured. Kindly update the field else clarify.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 10:58:50
Query 'Per CDM: It was mentioned for "Were any prior/concomitant medications and/or vaccinations taken?" as "No". However, Concomitant medications were captured. Kindly update the field else clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 17:56:55
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 17:56:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Dec 2020 17:37:36
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 21:02:35
User opened query 'Per CDM: It was mentioned for "Were any prior/concomitant medications and/or vaccinations taken?" as "No". However, Concomitant medications were captured. Kindly update the field else clarify.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 08:38:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 17:58:26
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:51:02

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	31 Aug 2020 04:45:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	31 Aug 2020 04:45:42
Data point term sent to Coder	System	30 Aug 2020 18:52:48
User entered 'Aspirin'	Alisha Lutat (b) (4)	30 Aug 2020 18:52:08

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:52:08

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'CVA'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:52:08

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '81'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:52:08

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'mg (mg)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:52:08

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:52:08

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'once daily (QD)'	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 18:52:08

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:52:08

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'Oral (ORAL)'	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 18:52:08

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:52:08

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'UN Feb 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:52:08

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:52:08

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
Query 'Per DM CLR RQ: Response noted. However please provide clarification for continued use of medication as the corresponding MH/AE has resolved.' canceled (Site from DM).	(b) (4) (u) (4), (b) (6)	28 Mar 2021 02:47:44
User opened query 'Per DM CLR RQ: Response noted. However please provide clarification for continued use of medication as the corresponding MH/AE has resolved.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 06:32:12
User closed query 'Per DM CLR: The corresponding MH/AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or MH/AE as appropriate. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 02:39:44
Query 'Per DM CLR: The corresponding MH/AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or MH/AE as appropriate. Otherwise, provide clarification for continued use of medication.' answered with 'Per source, con med is ongoing.' (Site from DM).	Alisha Lutat (b) (4) (b) (4)	23 Mar 2021 15:51:15
User opened query 'Per DM CLR: The corresponding MH/AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or MH/AE as appropriate. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 00:39:28
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:52:08

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 18:52:08

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Aug 2020 18:52:47
User entered 'No (N)' reason for change: Data Entry Error	System	30 Aug 2020 18:52:47
User opened query 'Data is required. Please complete.' (Site from System).	Alisha Lutat (b) (4)	30 Aug 2020 18:52:47
User entered empty.	(b) (4)	
	System	30 Aug 2020 18:52:08
	Alisha Lutat (b) (4)	30 Aug 2020 18:52:08
	(b) (4)	

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered 'I'	System	30 Aug 2020 18:52:08

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered 'I'	System	30 Aug 2020 18:52:08

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered '804 (804)'	System	30 Aug 2020 18:52:08

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:40
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 21:04:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 21:04:48
Data point term sent to Coder	System	16 Nov 2020 21:04:08
User entered 'Influenza vaccine'	(b) (4), (b) (6)	16 Nov 2020 21:03:30

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:40
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 21:03:30

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:40
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'Flu prevention'	(b) (4) (u) (4), (b) (6)	16 Nov 2020 21:03:30

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:40
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0.5'	(b) (4) (u) (4), (b) (6)	16 Nov 2020 21:03:30

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:40
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'mL (mL)'	(b) (4) (u) (4), (b) (6)	16 Nov 2020 21:03:30

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:40
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) (u) (4), (b) (6)	16 Nov 2020 21:03:30

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:40
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	(b) (4) System	27 Jan 2021 05:31:37
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	16 Nov 2020 21:03:30
User entered 'once (ONCE)'	(b) (4), (b) (6)	16 Nov 2020 21:03:30

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:40
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty; reason for change Data Entry Error	(b) (4) (u) (4), (b) (6)	27 Jan 2021 05:31:37
User entered 'Once a year/seasonal'	(b) (4), (b) (6)	16 Nov 2020 21:03:30

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:40
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (u) (4), (b) (6)	16 Nov 2020 21:03:30

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:40
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) (u) (4), (b) (6)	16 Nov 2020 21:03:30

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:40
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '21 Oct 2020'	(b) (4) (u) (4), (b) (6)	16 Nov 2020 21:03:30

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:40
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0'	(b) (4) (u) (4), (b) (6)	16 Nov 2020 21:03:30

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:40
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	16 Nov 2020 21:03:30

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:40
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '21 Oct 2020'	(b) (4) (u) (4), (b) (6)	16 Nov 2020 21:03:30

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:40
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	16 Nov 2020 21:03:30

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:40
User entered empty.	System	16 Nov 2020 21:03:30

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:40
User entered empty.	System	16 Nov 2020 21:03:30

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:40
User entered empty.	System	16 Nov 2020 21:03:30

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:42
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (u) (4), (b) (6)	04 Mar 2021 09:17:15
Query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' answered with 'checked "CM" for other action taken on AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 07:25:34
User opened query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 02:27:38
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN HEMIHYDRATE, PRODUCTSYNONYM: LEVONOX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 14:15:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 14:15:47
Data point term sent to Coder	System	10 Feb 2021 00:46:33
User entered 'Levonox'	(b) (4), (b) (6)	10 Feb 2021 00:46:05

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:42
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	10 Feb 2021 00:46:05

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:42
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'CVA'	(b) (4) (u) (4), (b) (6)	10 Feb 2021 00:46:05

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:42
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '40'	(b) (4) (u) (4), (b) (6)	10 Feb 2021 00:46:05

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:42
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'mg (mg)'	(b) (4) (u) (4), (b) (6)	10 Feb 2021 00:46:05

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:42
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) (u) (4), (b) (6)	10 Feb 2021 00:46:05

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:42
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'once daily (QD)'	(b) (4) (u) (4), (b) (6)	10 Feb 2021 00:46:05

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:42
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) (u) (4), (b) (6)	10 Feb 2021 00:46:05

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:42
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (u) (4), (b) (6)	10 Feb 2021 00:46:05

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:42
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered empty.	(b) (4) (u) (4), (b) (6)	10 Feb 2021 00:46:05

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:42
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '3 Jan 2021'	(b) (4) (u) (4), (b) (6)	10 Feb 2021 00:46:05

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:42
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '0'	(b) (4) (u) (4), (b) (6)	10 Feb 2021 00:46:05

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:42
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'Per DM CLR RQ: Please consider to leave the query open till the CM stop date can be verified and updated.' (Site from DM).	(b) (4)	07 Apr 2021 02:20:52
Query 'Per DM CLR RQ: Please consider to leave the query open till the CM stop date can be verified and updated.' answered with 'Data updated' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 14:49:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 14:48:36
User opened query 'Per DM CLR RQ: Please consider to leave the query open till the CM stop date can be verified and updated.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 02:41:25
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 02:41:25
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'Pt to be contacted to verify end date of conmed ' (Site from DM).	Alisha Lutat (b) (4)	23 Mar 2021 18:52:53
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 02:27:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Feb 2021 00:46:05

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:42
User signature succeeded.	Milton Haber (b) (4) (b) (4)	11 Apr 2021 07:07:07
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	06 Apr 2021 14:48:53
User entered '12 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 14:48:53
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	06 Apr 2021 14:48:36
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 00:46:05

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:42
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Feb 2021 15:30:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Feb 2021 15:30:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 15:30:16
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 00:46:05
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 00:46:05

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:42
User entered 'I'	System	10 Feb 2021 00:46:05

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:42
User entered '1'	System	10 Feb 2021 00:46:05

US3572086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:42
User entered '804 (804)'	System	10 Feb 2021 00:46:05

US3572086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:18:18

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	(u) (4), (b) (6)	26 Feb 2021 18:15:13
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 17:58:37

US3572086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:18:18

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered '13 Jan 2021'	(b) (4) (u) (4), (b) (6)	12 Mar 2021 15:59:24

US3572086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:18:18

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered 'PHYSICAL AND OCCUPATIONAL THERAPY FOLLOWING CVA'	(b) (4) (u) (4), (b) (6)	12 Mar 2021 15:59:24

US3572086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:18:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered 'Adverse Event (AE)'	(b) (4) (u) (4), (b) (6)	12 Mar 2021 15:59:24

US3572086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:18:18

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered empty.	(b) (4) (u) (4), (b) (6)	12 Mar 2021 15:59:24

US3572086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:18:18

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:20
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered '05 Jan 2021'	(b) (4) (u) (4), (b) (6)	16 Mar 2021 15:11:08

US3572086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:18:18

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:20
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered 'COVID19 PLASMA'	(b) (4) (u) (4), (b) (6)	16 Mar 2021 15:11:08

US3572086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:18:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:20
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered 'Other (OTHER)'	(b) (4) (u) (4), (b) (6)	16 Mar 2021 15:11:08

US3572086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:18:18

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:20
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered 'COVID19 POSITIVE'	(b) (4) (u) (4), (b) (6)	16 Mar 2021 15:11:08

US3572086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:18:18

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:24
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	16 Mar 2021 15:56:14
User entered '01 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 15:56:14
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Mar 2021 15:47:32
User entered 'UN Jan 2021' (non-conformant).	(b) (4), (b) (6)	16 Mar 2021 15:47:32

US3572086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:18:18

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:24
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered 'O2 SUPPLEMENT'	(b) (4) (u) (4), (b) (6)	16 Mar 2021 15:47:32

US3572086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:18:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:24
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered 'Adverse Event (AE)'	(b) (4) (u) (4), (b) (6)	16 Mar 2021 15:47:32

US3572086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:18:18

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:24
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered empty.	(b) (4) (u) (4), (b) (6)	16 Mar 2021 15:47:32

US3572086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:18:18

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	16 Mar 2021 15:56:36
User entered '01 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 15:56:36
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Mar 2021 15:52:50
User entered 'un Jan 2021' (non-conformant).	(b) (4), (b) (6)	16 Mar 2021 15:52:50

US3572086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:18:18

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered 'INCENTIVE SPIROMETRY'	(b) (4) (u) (4), (b) (6)	16 Mar 2021 15:52:50

US3572086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:18:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered 'Adverse Event (AE)'	(b) (4) (u) (4), (b) (6)	16 Mar 2021 15:52:50

US3572086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:18:18

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered empty.	(b) (4) (u) (4), (b) (6)	16 Mar 2021 15:52:50

US3572086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:18:18

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:31
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	16 Mar 2021 15:57:12
User entered '01 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 15:57:12
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Mar 2021 15:53:41
User entered 'UN Jan 2021' (non-conformant).	(b) (4), (b) (6)	16 Mar 2021 15:53:41

US3572086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:18:18

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:31
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered 'Remdesivir administered for 5 days'	(b) (4) (u) (4), (b) (6)	16 Mar 2021 15:53:41

US3572086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:18:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:31
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered 'Adverse Event (AE)'	(b) (4) (u) (4), (b) (6)	16 Mar 2021 15:53:41

US3572086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:18:18

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:31
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered empty.	(b) (4) (u) (4), (b) (6)	16 Mar 2021 15:53:41

US3572086

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:18:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:26:40
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
User entered '12 Feb 2021'	(b) (4) (u) (4), (b) (6)	20 Apr 2021 14:36:46

US3572086

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:18:18

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:26:40
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
User entered 'Death (DEATH)'	(b) (4) (u) (4), (b) (6)	20 Apr 2021 14:36:46

US3572086

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:18:18

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 06:26:40
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
User entered empty.	(b) (4) (u) (4), (b) (6)	20 Apr 2021 14:36:46

US3572086

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:18:18

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:26:40
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
User entered 'Adverse event (ADVERSE EVENT)'	(b) (4) (u) (4), (b) (6)	20 Apr 2021 14:36:46

US3572086

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:18:18

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:26:40
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
User entered empty.	(b) (4) (u) (4), (b) (6)	20 Apr 2021 14:36:46

US3572086

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:18:18

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:26:40
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
User entered '12 Feb 2021'	(b) (4) (u) (4), (b) (6)	20 Apr 2021 14:36:46

US3572086

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:18:18

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:26:40
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
User entered 'Unknown (UNK)'	(b) (4) (u) (4), (b) (6)	20 Apr 2021 14:36:46

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'USA-US091-2021-MRNA-1273-P301000001'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Yes (Y)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Yes (Y)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Milton'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Haber'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered '2344 Laguna Del Mar, Suite 201'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Laredo'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'TX'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered '78041'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'US'	System	20 Jan 2021 15:31:27

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered '9'	System	30 Apr 2021 15:33:44
User entered '8'	System	04 Mar 2021 17:10:14
User entered '7'	System	02 Mar 2021 14:34:59
User entered '6'	System	26 Feb 2021 14:44:23
User entered '5'	System	11 Feb 2021 13:08:46
User entered '4'	System	10 Feb 2021 16:44:37
User entered '3'	System	03 Feb 2021 20:14:00
User entered '2'	System	21 Jan 2021 19:38:24
User entered '1'	System	20 Jan 2021 15:31:27

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'USA-US091-2021-MRNA-1273-P301000001'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Yes (Y)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Yes (Y)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Milton'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Haber'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered '2344 Laguna Del Mar, Suite 201'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Laredo'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'TX'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered '78041'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'US'	System	20 Jan 2021 15:31:27

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered '9'	System	30 Apr 2021 15:33:44
User entered '8'	System	04 Mar 2021 17:10:14
User entered '7'	System	02 Mar 2021 14:34:59
User entered '6'	System	26 Feb 2021 14:44:23
User entered '5'	System	11 Feb 2021 13:08:46
User entered '4'	System	10 Feb 2021 16:44:37
User entered '3'	System	03 Feb 2021 20:14:00
User entered '2'	System	21 Jan 2021 19:38:24
User entered '1'	System	20 Jan 2021 15:31:27

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:18:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered '20/Jan/2021 10:31'	(b) (4) System	20 Jan 2021 15:31:27

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:18:18

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 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'I'	(b) (4), (b) (6)	20 Jan 2021 15:31:27

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'USA-US091-2021-MRNA-1273-P301000001'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Yes (Y)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Yes (Y)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Milton'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Haber'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered '2344 Laguna Del Mar, Suite 201'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Laredo'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'TX'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered '78041'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'US'	System	20 Jan 2021 15:31:27

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered '9'	System	30 Apr 2021 15:33:44
User entered '8'	System	04 Mar 2021 17:10:14
User entered '7'	System	02 Mar 2021 14:34:59
User entered '6'	System	26 Feb 2021 14:44:23
User entered '5'	System	11 Feb 2021 13:08:46
User entered '4'	System	10 Feb 2021 16:44:37
User entered '3'	System	03 Feb 2021 20:14:00
User entered '2'	System	21 Jan 2021 19:38:24
User entered '1'	System	20 Jan 2021 15:31:27

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:18:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered '21/Jan/2021 14:38'	(b) (4) System	21 Jan 2021 19:38:24

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:18:18

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 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	21 Jan 2021 19:38:28
User entered 'I'	(b) (4), (b) (6)	21 Jan 2021 19:38:24

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'USA-US091-2021-MRNA-1273-P301000001'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Yes (Y)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Yes (Y)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Milton'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Haber'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered '2344 Laguna Del Mar, Suite 201'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Laredo'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'TX'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered '78041'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'US'	System	20 Jan 2021 15:31:27

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered '9'	System	30 Apr 2021 15:33:44
User entered '8'	System	04 Mar 2021 17:10:14
User entered '7'	System	02 Mar 2021 14:34:59
User entered '6'	System	26 Feb 2021 14:44:23
User entered '5'	System	11 Feb 2021 13:08:46
User entered '4'	System	10 Feb 2021 16:44:37
User entered '3'	System	03 Feb 2021 20:14:00
User entered '2'	System	21 Jan 2021 19:38:24
User entered '1'	System	20 Jan 2021 15:31:27

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:18:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered '03/Feb/2021 20:13'	(b) (4) System	03 Feb 2021 20:14:00

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:18:18

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 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:44:24
User entered 'I'	(b) (4), (b) (6)	03 Feb 2021 20:14:00

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'USA-US091-2021-MRNA-1273-P301000001'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Yes (Y)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Yes (Y)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Milton'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Haber'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered '2344 Laguna Del Mar, Suite 201'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Laredo'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'TX'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered '78041'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'US'	System	20 Jan 2021 15:31:27

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered '9'	System	30 Apr 2021 15:33:44
User entered '8'	System	04 Mar 2021 17:10:14
User entered '7'	System	02 Mar 2021 14:34:59
User entered '6'	System	26 Feb 2021 14:44:23
User entered '5'	System	11 Feb 2021 13:08:46
User entered '4'	System	10 Feb 2021 16:44:37
User entered '3'	System	03 Feb 2021 20:14:00
User entered '2'	System	21 Jan 2021 19:38:24
User entered '1'	System	20 Jan 2021 15:31:27

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:18:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered '10/Feb/2021 16:44'	(b) (4) System	10 Feb 2021 16:44:37

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:18:18

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 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 13:08:32
User entered 'I'	(b) (4), (b) (6)	10 Feb 2021 16:44:37

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'USA-US091-2021-MRNA-1273-P301000001'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Yes (Y)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Yes (Y)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Milton'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Haber'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered '2344 Laguna Del Mar, Suite 201'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Laredo'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'TX'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered '78041'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'US'	System	20 Jan 2021 15:31:27

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered '9'	System	30 Apr 2021 15:33:44
User entered '8'	System	04 Mar 2021 17:10:14
User entered '7'	System	02 Mar 2021 14:34:59
User entered '6'	System	26 Feb 2021 14:44:23
User entered '5'	System	11 Feb 2021 13:08:46
User entered '4'	System	10 Feb 2021 16:44:37
User entered '3'	System	03 Feb 2021 20:14:00
User entered '2'	System	21 Jan 2021 19:38:24
User entered '1'	System	20 Jan 2021 15:31:27

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:18:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered '11/Feb/2021 08:08'	(b) (4) System	11 Feb 2021 13:08:46

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:18:18

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 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:05:56
User entered 'I'	(b) (4), (b) (6)	11 Feb 2021 13:08:46

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'USA-US091-2021-MRNA-1273-P301000001'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Yes (Y)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Yes (Y)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Milton'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Haber'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered '2344 Laguna Del Mar, Suite 201'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Laredo'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'TX'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered '78041'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'US'	System	20 Jan 2021 15:31:27

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered '9'	System	30 Apr 2021 15:33:44
User entered '8'	System	04 Mar 2021 17:10:14
User entered '7'	System	02 Mar 2021 14:34:59
User entered '6'	System	26 Feb 2021 14:44:23
User entered '5'	System	11 Feb 2021 13:08:46
User entered '4'	System	10 Feb 2021 16:44:37
User entered '3'	System	03 Feb 2021 20:14:00
User entered '2'	System	21 Jan 2021 19:38:24
User entered '1'	System	20 Jan 2021 15:31:27

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:18:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered '26/Feb/2021 14:44'	(b) (4) System	26 Feb 2021 14:44:23

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:18:18

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 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:34:46
User entered 'I'	(b) (4), (b) (6)	26 Feb 2021 14:44:23

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'USA-US091-2021-MRNA-1273-P301000001'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Yes (Y)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Yes (Y)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Milton'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Haber'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered '2344 Laguna Del Mar, Suite 201'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Laredo'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'TX'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered '78041'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'US'	System	20 Jan 2021 15:31:27

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered '9'	System	30 Apr 2021 15:33:44
User entered '8'	System	04 Mar 2021 17:10:14
User entered '7'	System	02 Mar 2021 14:34:59
User entered '6'	System	26 Feb 2021 14:44:23
User entered '5'	System	11 Feb 2021 13:08:46
User entered '4'	System	10 Feb 2021 16:44:37
User entered '3'	System	03 Feb 2021 20:14:00
User entered '2'	System	21 Jan 2021 19:38:24
User entered '1'	System	20 Jan 2021 15:31:27

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:18:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered '02/Mar/2021 08:34'	(b) (4) System	02 Mar 2021 14:34:59

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:18:18

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 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	04 Mar 2021 17:10:49
User entered 'I'	(b) (4), (b) (6)	02 Mar 2021 14:34:59

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'USA-US091-2021-MRNA-1273-P301000001'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Yes (Y)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Yes (Y)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Milton'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Haber'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered '2344 Laguna Del Mar, Suite 201'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Laredo'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'TX'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered '78041'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'US'	System	20 Jan 2021 15:31:27

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered '9'	System	30 Apr 2021 15:33:44
User entered '8'	System	04 Mar 2021 17:10:14
User entered '7'	System	02 Mar 2021 14:34:59
User entered '6'	System	26 Feb 2021 14:44:23
User entered '5'	System	11 Feb 2021 13:08:46
User entered '4'	System	10 Feb 2021 16:44:37
User entered '3'	System	03 Feb 2021 20:14:00
User entered '2'	System	21 Jan 2021 19:38:24
User entered '1'	System	20 Jan 2021 15:31:27

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 08:18:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered '04/Mar/2021 12:10'	(b) (4) System	04 Mar 2021 17:10:14

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 08:18:18

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 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	04 Mar 2021 17:10:49
User entered 'I'	(b) (4), (b) (6)	04 Mar 2021 17:10:14

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'USA-US091-2021-MRNA-1273-P301000001'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Yes (Y)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Yes (Y)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'No (N)'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Milton'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Haber'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered '2344 Laguna Del Mar, Suite 201'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'Laredo'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'TX'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered '78041'	System	20 Jan 2021 15:30:31

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	20 Jan 2021 15:31:31
User entered 'US'	System	20 Jan 2021 15:31:27

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered '9'	System	30 Apr 2021 15:33:44
User entered '8'	System	04 Mar 2021 17:10:14
User entered '7'	System	02 Mar 2021 14:34:59
User entered '6'	System	26 Feb 2021 14:44:23
User entered '5'	System	11 Feb 2021 13:08:46
User entered '4'	System	10 Feb 2021 16:44:37
User entered '3'	System	03 Feb 2021 20:14:00
User entered '2'	System	21 Jan 2021 19:38:24
User entered '1'	System	20 Jan 2021 15:31:27

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 08:18:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	30 Apr 2021 16:37:40
User entered '30/Apr/2021 11:33'	(b) (4) System	30 Apr 2021 15:33:44

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 08:18:18

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 17:19:09
User signature succeeded.	Milton Haber (b) (4)	30 Apr 2021 16:37:40
User entered 'I'	(b) (4) (u) (4), (b) (6)	30 Apr 2021 15:33:44

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'USA-US091-2021-MRNA-1273-P301000015'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'Yes (Y)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'Yes (Y)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'No (N)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:29:55
Un-reviewed for Safety.	System	27 Mar 2021 03:10:44
User entered 'Yes (Y)'	System	27 Mar 2021 03:10:44
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'No (N)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'No (N)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'No (N)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'No (N)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'Milton'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'Haber'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered '2344 Laguna Del Mar, Suite 201'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'Laredo'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'TX'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered '78041'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:29:55
User entered 'US'	System	26 Mar 2021 22:47:37

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered '5'	System	26 Apr 2021 17:08:12
User entered '4'	System	15 Apr 2021 18:40:57
User entered '3'	System	07 Apr 2021 17:03:28
User entered '2'	System	29 Mar 2021 16:30:08
User entered '1'	System	26 Mar 2021 22:47:37

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'USA-US091-2021-MRNA-1273-P301000015'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'Yes (Y)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'Yes (Y)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'No (N)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:29:55
Un-reviewed for Safety.	System	27 Mar 2021 03:10:44
User entered 'Yes (Y)'	System	27 Mar 2021 03:10:44
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'No (N)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'No (N)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'No (N)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.		20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'No (N)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'Milton'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'Haber'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered '2344 Laguna Del Mar, Suite 201'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'Laredo'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'TX'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered '78041'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:29:55
User entered 'US'	System	26 Mar 2021 22:47:37

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered '5'	System	26 Apr 2021 17:08:12
User entered '4'	System	15 Apr 2021 18:40:57
User entered '3'	System	07 Apr 2021 17:03:28
User entered '2'	System	29 Mar 2021 16:30:08
User entered '1'	System	26 Mar 2021 22:47:37

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:18:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered '26/Mar/2021 22:47'	(b) (4) System	26 Mar 2021 22:47:37

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:18:18

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 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:29:55
User entered 'I'	(b) (4), (b) (6)	26 Mar 2021 22:47:37

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'USA-US091-2021-MRNA-1273-P301000015'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'Yes (Y)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'Yes (Y)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'No (N)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:29:55
Un-reviewed for Safety.	System	27 Mar 2021 03:10:44
User entered 'Yes (Y)'	System	27 Mar 2021 03:10:44
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'No (N)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'No (N)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'No (N)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'No (N)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'Milton'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'Haber'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered '2344 Laguna Del Mar, Suite 201'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'Laredo'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'TX'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered '78041'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:29:55
User entered 'US'	System	26 Mar 2021 22:47:37

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered '5'	System	26 Apr 2021 17:08:12
User entered '4'	System	15 Apr 2021 18:40:57
User entered '3'	System	07 Apr 2021 17:03:28
User entered '2'	System	29 Mar 2021 16:30:08
User entered '1'	System	26 Mar 2021 22:47:37

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:18:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered '29/Mar/2021 11:30'	(b) (4) System	29 Mar 2021 16:30:08

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:18:18

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 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 17:03:08
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
User entered 'I'	(b) (4) (u) (4), (b) (6)	29 Mar 2021 16:30:08

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'USA-US091-2021-MRNA-1273-P301000015'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'Yes (Y)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'Yes (Y)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'No (N)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:29:55
Un-reviewed for Safety.	System	27 Mar 2021 03:10:44
User entered 'Yes (Y)'	System	27 Mar 2021 03:10:44
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'No (N)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'No (N)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'No (N)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'No (N)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'Milton'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'Haber'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered '2344 Laguna Del Mar, Suite 201'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'Laredo'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'TX'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered '78041'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:29:55
User entered 'US'	System	26 Mar 2021 22:47:37

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered '5'	System	26 Apr 2021 17:08:12
User entered '4'	System	15 Apr 2021 18:40:57
User entered '3'	System	07 Apr 2021 17:03:28
User entered '2'	System	29 Mar 2021 16:30:08
User entered '1'	System	26 Mar 2021 22:47:37

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:18:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered '07/Apr/2021 13:03'	(b) (4) System	07 Apr 2021 17:03:28

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:18:18

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 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:07:07
User entered 'l'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:03:28

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'USA-US091-2021-MRNA-1273-P301000015'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'Yes (Y)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'Yes (Y)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'No (N)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:29:55
Un-reviewed for Safety.	System	27 Mar 2021 03:10:44
User entered 'Yes (Y)'	System	27 Mar 2021 03:10:44
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'No (N)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'No (N)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'No (N)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'No (N)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'Milton'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'Haber'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered '2344 Laguna Del Mar, Suite 201'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'Laredo'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'TX'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered '78041'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:29:55
User entered 'US'	System	26 Mar 2021 22:47:37

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered '5'	System	26 Apr 2021 17:08:12
User entered '4'	System	15 Apr 2021 18:40:57
User entered '3'	System	07 Apr 2021 17:03:28
User entered '2'	System	29 Mar 2021 16:30:08
User entered '1'	System	26 Mar 2021 22:47:37

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:18:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:53
User entered '15/Apr/2021 14:40'	(b) (4) System	15 Apr 2021 18:40:57

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:18:18

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 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:53
User entered 'l'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 18:40:57

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'USA-US091-2021-MRNA-1273-P301000015'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'Yes (Y)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'Yes (Y)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'No (N)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:29:55
Un-reviewed for Safety.	System	27 Mar 2021 03:10:44
User entered 'Yes (Y)'	System	27 Mar 2021 03:10:44
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'No (N)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'No (N)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'No (N)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'No (N)'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'Milton'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'Haber'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered '2344 Laguna Del Mar, Suite 201'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'Laredo'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

Site Address: [State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered 'TX'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 22:47:25
User entered '78041'	System	26 Mar 2021 22:46:52

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:40
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:25:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:29:55
User entered 'US'	System	26 Mar 2021 22:47:37

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User entered '5'	System	26 Apr 2021 17:08:12
User entered '4'	System	15 Apr 2021 18:40:57
User entered '3'	System	07 Apr 2021 17:03:28
User entered '2'	System	29 Mar 2021 16:30:08
User entered '1'	System	26 Mar 2021 22:47:37

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:18:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
User entered '26/Apr/2021 13:08'	(b) (4) System	26 Apr 2021 17:08:12

US3572086

Folder: SAE USA-US091-2021-MRNA-1273-P301000015

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:18:18

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 17:19:09
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:05:02
User entered 'l'	(b) (4) (u) (4), (b) (6)	26 Apr 2021 17:08:12