

US3572076 (Prod: Laguna Clinical Research Associates)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3572076

Form: Participant Creation

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

[Participant ID](#)

US3572076

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

US3572076

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Date of Birth (MMM yyyy)	(b) (6) 2000
Age	19
Age Units	YEARS
Age (Derived)	19
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 20 Mar 2021 23:47:53

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Date of Informed Consent (<i>dd MMM yyyy</i>)	24 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 20 Mar 2021 23:47:53

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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 23:47:53

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 20 Mar 2021 23:47:53

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Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN JUN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	11:40 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 11:40
Height (xxx.x)	64 in
Weight (xxx.x)	118.8 lb
BMI (xxx.x)	20.43461 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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 23:47:53

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 20 Mar 2021 23:47:53

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Date of assessment (dd MMM yyyy) 24 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) _____

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	24 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Mar 2021 23:47:53

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Mar 2021 23:47:53

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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) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

What was the date of randomization? (dd MMM yyyy) 24 AUG 2020

What was the participant's randomization number? 107714

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) 20 Mar 2021 23:47:53

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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) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	11:50 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 11:50
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	13:11 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 13:11
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

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) 24 AUG 2020

What was the treatment time? (00:00-23:59) 12:31 (24 HR)

Treatment Date and Time (derived) 24 AUG 2020 12:31

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) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 AUG 2020

Collection time (00:00-23:59)

12:00 (24 HR)

Collection date and time (derived)

24 AUG 2020 12:00

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Collection date (dd MMM yyyy)			24 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:25	24 AUG 2020 12:25
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

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 08:17:25

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

24 AUG 2020 13:17

PC Open Date & Time

24 AUG 2020 12:51

PC Close Date & Time

24 AUG 2020 15:21

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

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 98.1 °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 11:06
PC Open Date & Time	24 AUG 2020 16:16
PC Close Date & Time	25 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 10:14

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 09:26

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(4)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 10:08

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(5)

Generated On: 10 Jun 2021 08:17:25

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 11:20

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:25

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:25

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 12:25

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

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

24 AUG 2020 13:18

PC Open Date & Time

24 AUG 2020 12:51

PC Close Date & Time

24 AUG 2020 15:21

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

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 11:06

PC Open Date & Time

24 AUG 2020 16:16

PC Close Date & Time

25 AUG 2020 11:59

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:25

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 10:14

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:25

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 09:26

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:25

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 10:08

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:25

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 11:20

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:25

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 ☐

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

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

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:25

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

30 AUG 2020 12:25

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

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 ☐

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 13:54
PC Open Date & Time	24 AUG 2020 12:51
PC Close Date & Time	24 AUG 2020 15:21

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

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 ☐

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 11:07
PC Open Date & Time	24 AUG 2020 16:16
PC Close Date & Time	25 AUG 2020 11:59

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:25

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 ☒

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:25

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 10:15
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:25

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)

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:25

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 09:35
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:25

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

49 of 2300

EAB) (1725)

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:25

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 10:09
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:25

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 2300

EAB) (1725)

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:25

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 11:20
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:25

Yes ☐

PC Time stamp

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:25

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 2300

EAB) (1725)

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:25

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 12:25
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3572076

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

31 AUG 2020 13:36

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3572076

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

31 AUG 2020 13:36

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3572076

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	31 AUG 2020 13:36
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3572076

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572076

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572076

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 SEP 2020

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

Comments
If Contact Not Made, please provide Comments
VOICEMAIL BOX NOT SET UP.
TEXT MESSAGE SENT TO
DETERMINE AVAILABILITY OF
PATIENT

US3572076

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Mar 2021 23:47:52

Generated On: 10 Jun 2021 08:17:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572076

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Was Contact Attempted? Yes ☒ No ☐

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

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

Comments VOICEMAIL BOX NOT SET UP.
TEXT MESSAGE SENT TO
If Contact Not Made, please provide Comments DETERMINE AVAILABILITY

US3572076

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572076

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 SEP 2020
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 11:25
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 SEP 2020
Time of assessment (00:00-23:59)	12:43 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 12:43
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3572076

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 SEP 2020

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

US3572076

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	22 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3572076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

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) 22 SEP 2020

What was the treatment time? (00:00-23:59) 12:13 (24 HR)

Treatment Date and Time (derived) 22 SEP 2020 12:13

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

US3572076

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 SEP 2020

Collection time (00:00-23:59)

11:28 (24 HR)

Collection date and time (derived)

22 SEP 2020 11:28

US3572076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Collection date (dd MMM yyyy)			22 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:58	22 SEP 2020 10:58
Nasopharyngeal Swab 2	No		

US3572076

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 12:50

PC Open Date & Time

22 SEP 2020 12:33

PC Close Date & Time

22 SEP 2020 15:03

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

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 98.1 °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	22 SEP 2020 23:59
PC Open Date & Time	22 SEP 2020 15:58
PC Close Date & Time	23 SEP 2020 11:59

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

23 SEP 2020 16:47

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:25

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

97.1 °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

24 SEP 2020 15:15

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 23:59

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:25

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

26 SEP 2020 13:57

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 20:23

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:25

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

98.1 °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 SEP 2020 00:47

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

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

22 SEP 2020 12:50

PC Open Date & Time

22 SEP 2020 12:33

PC Close Date & Time

22 SEP 2020 15:03

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

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

22 SEP 2020 23:59

PC Open Date & Time

22 SEP 2020 15:58

PC Close Date & Time

23 SEP 2020 11:59

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:25

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

23 SEP 2020 16:48

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:25

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

24 SEP 2020 15:15

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:25

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

25 SEP 2020 23:59

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:25

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

26 SEP 2020 13:58

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:25

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

27 SEP 2020 20:23

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:25

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 00:47

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

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 ☐

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 12:51
PC Open Date & Time	22 SEP 2020 12:33
PC Close Date & Time	22 SEP 2020 15:03

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

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 ☐

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 23:59
PC Open Date & Time	22 SEP 2020 15:58
PC Close Date & Time	23 SEP 2020 11:59

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:25

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 ☒

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:25

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 16:48
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:25

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 15:15
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:25

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)

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:25

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 23:59
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:25

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

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:25

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 13:58
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:25

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 20:23
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:25

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 00:47
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3572076

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

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

US3572076

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572076

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

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

US3572076

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572076

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572076

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572076

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3572076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 OCT 2020
Time of assessment (00:00-23:59)	09:30 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 09:30
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3572076

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 OCT 2020

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

US3572076

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 OCT 2020
Collection time (00:00-23:59)	09:41 (24 HR)
Collection date and time (derived)	21 OCT 2020 09:41

US3572076

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 20 Mar 2021 23:47:53

Generated On: 10 Jun 2021 08:17:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 OCT 2020 00:03:34
Patient Cloud Open Date & Time	24 OCT 2020 00:01
Patient Cloud Close Date & Time	28 OCT 2020 23:59

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

[Patient Cloud Open Date & Time](#)

25 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

[Patient Cloud Open Date & Time](#)

02 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2020 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

[Patient Cloud Open Date & Time](#)

09 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2020 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 DEC 2020 15:19:10
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	23 DEC 2020 03:15:59
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 DEC 2020 00:04:57
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 JAN 2021 00:01:32

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 JAN 2021 13:34:32

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 00:01:24

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 JAN 2021 12:01:09
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 00:18:19

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 FEB 2021 12:55:33

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 FEB 2021 00:55:10
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 FEB 2021 00:04:33
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAR 2021 06:01:24
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 MAR 2021 00:03:41
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 MAR 2021 00:02:22

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 12:00:35

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 MAR 2021 00:02:29

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 APR 2021 17:54:28

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 11:18:32

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 18:09:13

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 APR 2021 01:29:50

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 257

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

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

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

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

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

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

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 ☐

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 271

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

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

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

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

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

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

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 ☐

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 418

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 FEB 2022 00:01
Patient Cloud Close Date & Time	06 FEB 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 FEB 2022 00:01
Patient Cloud Close Date & Time	27 FEB 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 607

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

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

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

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

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

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

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 ☐

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 635

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

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

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

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

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

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

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 ☐

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

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05 JUN 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

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12 JUN 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

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19 JUN 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 670

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

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

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

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

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

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

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 ☐

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

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03 JUL 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 691

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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13 JUL 2022 00:01

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17 JUL 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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20 JUL 2022 00:01

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24 JUL 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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31 JUL 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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07 AUG 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

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US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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21 AUG 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

[Patient Cloud Open Date & Time](#)

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28 AUG 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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04 SEP 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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11 SEP 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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18 SEP 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 761

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

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

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

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

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

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

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 ☐

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

DAY 796

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

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

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

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

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

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

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 ☐

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2022 23:59

US3572076

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:17:25

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		03 MAR 2021 06:01:38

US3572076

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 04:12:37

Generated On: 10 Jun 2021 08:17:25

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 DEC 2020

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

Comments PREVIOUSLY UNABLE TO
REACH. NUMBER WAS
If Contact Not Made, please provide Comments DISCONNECTED. SUBJECT
CALLED SITE TODAY AND
UPDATED NUMBER

US3572076

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 04:12:37

Generated On: 10 Jun 2021 08:17:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572076

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572076

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572076

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

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

If Contact Not Made, please provide Comments

US3572076

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572076

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572076

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572076

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

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 _____

US3572076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
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 <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
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)	

US3572076

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:25

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.

US3572076

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:25

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

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

Collection date and time (derived)

US3572076

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:04:45

Generated On: 10 Jun 2021 08:17:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572076

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:40:29

Generated On: 10 Jun 2021 08:17:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572076

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:04:45

Generated On: 10 Jun 2021 08:17:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572076

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

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

US3572076

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 11 Apr 2021 07:06:46

Generated On: 10 Jun 2021 08:17:25

Date of Contact	1 SEP 2020
Time of Contact	16:00
Date and Time of Contact (derived)	1 SEP 2020 16:00
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input checked="" type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 11 Apr 2021 07:06:46

Generated On: 10 Jun 2021 08:17:25

Symptom Day

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

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 11 Apr 2021 07:06:46

Generated On: 10 Jun 2021 08:17:25

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

Date	1 SEP 2020
------	------------

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

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

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

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

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

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

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

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

327 of 2300

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 11 Apr 2021 07:06:46

Generated On: 10 Jun 2021 08:17:25

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

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 11 Apr 2021 07:06:46

Generated On: 10 Jun 2021 08:17:25

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

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 11 Apr 2021 07:06:44

Generated On: 10 Jun 2021 08:17:25

Date of Visit	1 SEP 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	1 SEP 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 11 Apr 2021 07:06:46

Generated On: 10 Jun 2021 08:17:25

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3572076

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

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

US3572076

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 13 Apr 2021 04:31:37

Generated On: 10 Jun 2021 08:17:25

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

US3572076

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 15 Apr 2021 19:13:52

Generated On: 10 Jun 2021 08:17:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Apr 2021 04:31:38

Generated On: 10 Jun 2021 08:17:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 SEP 2020
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3572076

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 SEP 2020

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

US3572076

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

01 SEP 2020

US3572076

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 13 Apr 2021 04:31:37

Generated On: 10 Jun 2021 08:17:25

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

Visit date (dd MMM yyyy)

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

Folder OID	SICKD1
------------	--------

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Apr 2021 04:31:37

Generated On: 10 Jun 2021 08:17:25

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3572076

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Apr 2021 04:31:37

Generated On: 10 Jun 2021 08:17:25

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.

US3572076

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 13 Apr 2021 04:31:37

Generated On: 10 Jun 2021 08:17:25

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID SICKD28

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

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.

US3572076

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

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

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 13 Apr 2021 04:31:37

Generated On: 10 Jun 2021 08:17:25

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID SICKD28

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Apr 2021 04:31:37

Generated On: 10 Jun 2021 08:17:25

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Apr 2021 04:31:37

Generated On: 10 Jun 2021 08:17:25

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.

US3572076

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 13 Apr 2021 04:31:37

Generated On: 10 Jun 2021 08:17:25

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

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3572076

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

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

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

Visit date (dd MMM yyyy)	26 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3572076

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

Form: Unblinding

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

Date of updated informed consent (<i>dd MMM yyyy</i>)	26 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	26 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3572076

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

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

US3572076

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 FEB 2021
Time of assessment (00:00-23:59)	17:57 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 17:57
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	94 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	59 mmHg
Diastolic Blood Pressure units	MMHG

US3572076

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 FEB 2021
Time of assessment (00:00-23:59)	18:56 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 18:56
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3572076

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

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 FEB 2021

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

US3572076

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

Form: Pregnancy Test

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 25 FEB 2021

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3572076

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

Form: Exposure

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 25 FEB 2021

What was the treatment time? (00:00-23:59) 18:26 (24 HR)

Treatment Date and Time (derived) 25 FEB 2021 18:26

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

US3572076

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 JAN 2021
Collection time (00:00-23:59)	10:42 (24 HR)
Collection date and time (derived)	26 JAN 2021 10:42

US3572076

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 JAN 2021
Collection time (00:00 - 23:59)	10:29
Collection Date and Time (derived)	26 JAN 2021 10:29

US3572076

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

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572076

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag	1
-----------------	---

OLD29 Placebo Flag	1
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US3572076

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Apr 2021 19:13:52

Generated On: 10 Jun 2021 08:17:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Apr 2021 19:13:52

Generated On: 10 Jun 2021 08:17:25

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 APR 2021
Time of assessment (00:00-23:59)	14:40 (24 HR)
Vital Signs Date and Time (derived)	8 APR 2021 14:40
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
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)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Apr 2021 19:13:52

Generated On: 10 Jun 2021 08:17:25

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	
Pulse units	
Respiratory Rate (xxx)	
Respiratory Rate units	
Systolic Blood Pressure (xxx)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	
Diastolic Blood Pressure units	

US3572076

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Apr 2021 19:13:52

Generated On: 10 Jun 2021 08:17:25

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.

US3572076

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 15 Apr 2021 19:13:52

Generated On: 10 Jun 2021 08:17:25

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	8 APR 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input checked="" type="radio"/>
	Negative <input type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3572076

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 15 Apr 2021 19:13:52

Generated On: 10 Jun 2021 08:17:25

Was study treatment given? Yes ☐
No ☒

If No, reason not given

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

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

What was the study treatment? (Unblinded)

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3572076

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 15 Apr 2021 19:13:52

Generated On: 10 Jun 2021 08:17:25

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3572076

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3572076

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 10:04:45

Generated On: 10 Jun 2021 08:17:25

AEID

Adverse event

SORE/DRY THROAT

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)

29 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

4 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 10:04:45

Generated On: 10 Jun 2021 08:17:25

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

US3572076

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 10:04:45

Generated On: 10 Jun 2021 08:17:25

AEID	
Adverse event	BLOODY NOSE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	30 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 10:04:45

Generated On: 10 Jun 2021 08:17:25

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

US3572076

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 10:04:45

Generated On: 10 Jun 2021 08:17:25

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	24 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	4 SEP 2020
End time (00:00-23:59)	00:00 (24 HR)
AE End Date and Time (derived)	4 SEP 2020 00:00
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 10:04:45

Generated On: 10 Jun 2021 08:17:25

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

US3572076

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 28 Apr 2021 10:04:45

Generated On: 10 Jun 2021 08:17:25

AEID	
Adverse event	HOT FLASHES
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	24 AUG 2020
Start time (00:00-23:59)	00:00 (24 HR)
AE start date and time (derived)	24 AUG 2020 00:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	4 SEP 2020
End time (00:00-23:59)	00:00 (24 HR)
AE End Date and Time (derived)	4 SEP 2020 00:00
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 28 Apr 2021 10:04:45

Generated On: 10 Jun 2021 08:17:25

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

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 28 Apr 2021 10:04:45

Generated On: 10 Jun 2021 08:17:25

AEID

Adverse event

EXCESSIVE SWEATING

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

24 AUG 2020

Start time (00:00-23:59)

00:00 (24 HR)

AE start date and time (derived)

24 AUG 2020 00:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

4 SEP 2020

End time (00:00-23:59)

00:00 (24 HR)

AE End Date and Time (derived)

4 SEP 2020 00:00

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 28 Apr 2021 10:04:45

Generated On: 10 Jun 2021 08:17:25

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

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 28 Apr 2021 10:04:45

Generated On: 10 Jun 2021 08:17:25

AEID	
Adverse event	ITCHING AT THE INJECTION SITE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 FEB 2021
Start time (00:00-23:59)	10:00 (24 HR)
AE start date and time (derived)	26 FEB 2021 10:00
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 28 Apr 2021 10:04:45

Generated On: 10 Jun 2021 08:17:25

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	3 MM X 4 MM
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)	

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 28 Apr 2021 10:04:45

Generated On: 10 Jun 2021 08:17:25

AEID	USA-US091-2021-MRNA-1273-P30 1000016
Adverse event	PREGNANCY
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	8 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	16 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 28 Apr 2021 10:04:45

Generated On: 10 Jun 2021 08:17:25

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

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 28 Apr 2021 10:04:45

Generated On: 10 Jun 2021 08:17:25

SUBJECT PRESENTED TO THE
SITE FOR OL VISIT DAY 29,
URINE PREGNANCY WAS
DONE, THE TEST RESULT WAS
POSITIVE. THE SUBJECT WAS
NOT DOSED. THE EVENT HAS
BEEN REPORTED TO THE IRB
AND WILL BE REPORTED TO
PPD.

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)	

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

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

Yes ☒

No ☐

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

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

Name of Medication	TAYTULLA (ETHINYL ESTRADIOL / NORETHINDRONE)
--------------------	--

Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
-------------	--

Indication	CONTRACEPTIVE
------------	---------------

Dose per administration	20/1
-------------------------	------

Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
-----------	--

If dose unit is Other, specify	MCG / MG
--------------------------------	----------

Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
-----------	--

If frequency is Other, specify	
--------------------------------	--

Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>
-------------------------	---

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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) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

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

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 AUG 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

Name of Medication ALLERGY
MEDICATION-UNKNOWN
NAME

Prophylaxis Yes ☐
No ☒

Indication ALLERGIES

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		3 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3572076

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 03 Apr 2021 04:23:29

Generated On: 10 Jun 2021 08:17:25

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3572076

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:17:25

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

US3572076

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:17:25

Date of study discontinuation/completion (dd MMM yyyy)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3572076

Folder: SAE USA-US091-2021-MRNA-1273-P301000016

Form: Safety Report Form

Data signed: (b) (4) 13 Apr 2021 04:31:38

Generated On: 10 Jun 2021 08:17:25

SAEID	USA-US091-2021-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
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)	1

US3572076

Folder: SAE USA-US091-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Data signed: (b) (4) 13 Apr 2021 04:31:38

Generated On: 10 Jun 2021 08:17:25

SAEID	USA-US091-2021-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
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)	1
Date of submission (Pre-filled from custom function)	12/APR/2021 15:29
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3572076 (Prod: Laguna Clinical Research Associates)

US3572076

Form: Participant Creation

Generated On: 10 Jun 2021 08:17:25

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'US3572076'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 16:49:32

US3572076

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	24 Aug 2020 17:05:54

US3572076

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '24 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 16:49:33

US3572076

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[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 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Clinic (Clinic)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	24 Aug 2020 17:05:54

US3572076

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered 'SCRN'	System	24 Aug 2020 17:05:54

US3572076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:25

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered (b) (6) 2000'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 16:49:34

US3572076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:25

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '19'	(b) (4) Alisha Lutat (b) (4) (b) (4)	24 Aug 2020 17:06:50

US3572076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:25

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered 'YEARS'	System	24 Aug 2020 17:06:50

US3572076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:25

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered '19'	System	24 Aug 2020 17:14:04

US3572076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:25

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Female (F)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	24 Aug 2020 17:06:50

US3572076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:25

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) Alisha Lutat (b) (4)	24 Aug 2020 17:06:50

US3572076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:25

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'l'	(b) (4) Alisha Lutat (b) (4) (b) (4)	24 Aug 2020 17:06:50

US3572076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:25

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	24 Aug 2020 17:06:50

US3572076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:25

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	24 Aug 2020 17:06:50

US3572076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:25

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	24 Aug 2020 17:06:50

US3572076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:25

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	24 Aug 2020 17:06:50

US3572076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:25

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	24 Aug 2020 17:06:50

US3572076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:25

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty.	(b) (4) Alisha Lutat (b) (4)	24 Aug 2020 17:06:50

US3572076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:25

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	24 Aug 2020 17:06:50

US3572076

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:17:25

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	24 Aug 2020 17:06:50

US3572076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:25

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '24 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	24 Aug 2020 17:14:04

US3572076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered 'Aug 2020'	System	24 Aug 2020 17:14:04

US3572076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered '2020'	System	24 Aug 2020 17:14:04

US3572076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:25

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Amendment 2 (2)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	24 Aug 2020 17:14:04

US3572076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	24 Aug 2020 17:14:04

US3572076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	24 Aug 2020 17:14:04

US3572076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:25

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty.	(b) (4) Alisha Lutat (b) (4)	24 Aug 2020 17:14:04

US3572076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:25

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	24 Aug 2020 17:14:04

US3572076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:25

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 16:49:33

US3572076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:17:25

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered 'l'	System	24 Aug 2020 17:14:46

US3572076

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	24 Aug 2020 17:14:46

US3572076

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:17:25

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Alisha Lutat (b) (4)	22 Oct 2020 21:27:04
User entered 'No (N)' reason for change: Data Entry Error	Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:06:57
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	24 Aug 2020 17:15:27

US3572076

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 21:28:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 21:28:22
Data point term sent to Coder	System	22 Oct 2020 21:28:00
User entered 'Seasonal allergies'	Alisha Lutat (b) (4)	22 Oct 2020 21:27:25

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Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'UN Jun 2020'	(b) (4) Alisha Lutat (b) (4)	22 Oct 2020 21:27:25

US3572076

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:27:25

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Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:27:25

US3572076

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:27:25

US3572076

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:27:25

US3572076

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered 'Jun 2020'	System	22 Oct 2020 21:27:25

US3572076

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered '2020'	System	22 Oct 2020 21:27:25

US3572076

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered empty.	System	22 Oct 2020 21:27:25

US3572076

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered empty.	System	22 Oct 2020 21:27:25

US3572076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:08:44

US3572076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '24 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:08:44

US3572076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '11:40'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:08:44

US3572076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered '24 Aug 2020 11:40'	System	30 Aug 2020 15:08:44

US3572076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '64' in	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 15:08:44
DataPoint set to visible.	(b) (4) System	24 Aug 2020 17:14:46

US3572076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '118.8' lb	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 15:08:44
DataPoint set to visible.	(b) (4) System	24 Aug 2020 17:14:46

US3572076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered '20.43461'	System	30 Aug 2020 15:08:44
DataPoint set to visible.	System	24 Aug 2020 17:14:46

US3572076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered 'kg/m2'	System	30 Aug 2020 15:08:44
DataPoint set to visible.	System	24 Aug 2020 17:14:46

US3572076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 15:08:44

US3572076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:08:44

US3572076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:08:44

US3572076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 15:08:44

US3572076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered 'bpm'	System	30 Aug 2020 15:08:44

US3572076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 15:08:44

US3572076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered 'breaths/min'	System	30 Aug 2020 15:08:44

US3572076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:08:44

US3572076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered 'mmHg'	System	30 Aug 2020 15:08:44

US3572076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 15:08:44

US3572076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered 'mmHg'	System	30 Aug 2020 15:08:44

US3572076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59

US3572076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59

US3572076

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:08:58

US3572076

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:25

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '24 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:08:58

US3572076

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:17:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '24 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:09:42

US3572076

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:17:25

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:09:42

US3572076

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:17:25

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:09:42

US3572076

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:17:25

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:09:42

US3572076

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:17:25

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:09:42

US3572076

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:17:25

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:09:42

US3572076

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:09:42

US3572076

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:17:25

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:09:42

US3572076

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:11:06

US3572076

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '24 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:11:06

US3572076

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Urine (URINE)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:11:06

US3572076

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Negative (NEGATIVE)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:11:06

US3572076

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User closed query 'Per CDM: Was FSH sample collected? is No however collection date and time provide. Please reconcile and update appropriately.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 18:26:24
Query 'Per CDM: Was FSH sample collected? is No however collection date and time provide. Please reconcile and update appropriately.' answered with 'FSH collection date and time removed' (Site from DM).	Brett Potthoff (b) (4) (b) (4)	15 Sep 2020 00:17:05
User opened query 'Per CDM: Was FSH sample collected? is No however collection date and time provide. Please reconcile and update appropriately.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 11:29:07
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:11:06

US3572076

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty; reason for change Data Entry Error	(b) (4) Brett Potthoff (b) (4)	15 Sep 2020 00:16:52
User entered '24 Aug 2020'	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 15:11:06

US3572076

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty; reason for change Data Entry Error	(b) (4) Brett Potthoff (b) (4)	15 Sep 2020 00:16:52
User entered '12:05'	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 15:11:06

US3572076

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered empty.	System	15 Sep 2020 00:16:52
User entered '24 Aug 2020 12:05'	System	30 Aug 2020 15:11:06

US3572076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:25

[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 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:11:45

US3572076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:25

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 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:11:45

US3572076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:25

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 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:11:45

US3572076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:25

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 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:11:45

US3572076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:25

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 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:11:45

US3572076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:25

[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 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:11:45

US3572076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:25

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 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:11:45

US3572076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:25

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 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:11:45

US3572076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:25

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 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:11:45

US3572076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:25

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 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:11:45

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:25

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 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:11:45

US3572076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:25

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:11:45

US3572076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:25

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:11:45

US3572076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:25

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:11:45

US3572076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:11:45

US3572076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:25

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 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:11:45

US3572076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:25

[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 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:11:45

US3572076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:25

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 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:11:45

US3572076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'l'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:11:45

US3572076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:25

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:11:45

US3572076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:17:25

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:11:45

US3572076

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01SEP2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 07:48:00
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01SEP2020 is reported under Illness Visits 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)	29 Oct 2020 07:46:35
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	24 Aug 2020 17:44:37

US3572076

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '24 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	24 Aug 2020 17:44:37

US3572076

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Clinic (Clinic)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	24 Aug 2020 17:44:37

US3572076

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User entered 'VISIT1'	System	24 Aug 2020 17:44:37

US3572076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '24 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 16:59:44

US3572076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '107714'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 16:59:44

US3572076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 16:59:44

US3572076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:12:06

US3572076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 15:12:06

US3572076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:12:06

US3572076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:25

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:12:06

US3572076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:25

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:12:06

US3572076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4)	26 Oct 2020 11:01:58
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:40:05
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:40:30

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:25

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:25

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User accepted default value 'Pre-Dose (PREDOSE)'	Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '24 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '11:50'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User entered '24 Aug 2020 11:50'	System	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '97.7' F	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Other (Other)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Temporal'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '87'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User entered 'bpm'	System	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '18'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User entered 'breaths/min'	System	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '111'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User entered 'mmHg'	System	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '75'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User entered 'mmHg'	System	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:25

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User accepted default value 'Post-Dose (POSTDOSE)'	Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '24 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '13:11'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User entered '24 Aug 2020 13:11'	System	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '98.4' F	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Other (Other)'	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Temporal'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '75'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User entered 'bpm'	System	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '18'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User entered 'breaths/min'	System	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '101'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User entered 'mmHg'	System	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '72'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User entered 'mmHg'	System	30 Aug 2020 15:14:32

US3572076

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:14:52

US3572076

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '24 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:14:52

US3572076

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:15:03

US3572076

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:15:03

US3572076

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:15:03

US3572076

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:15:03

US3572076

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User closed query 'Per CDM: Response is required at this field. Please consider to update else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 05:00:40
Query 'Per CDM: Response is required at this field. Please consider to update else clarify.' answered with 'Corrected' (Site from DM).	Brett Potthoff (b) (4) (b) (4)	15 Sep 2020 00:38:32
User entered 'No (N)' reason for change: Data Entry Error	Brett Potthoff (b) (4) (b) (4)	15 Sep 2020 00:38:26
User opened query 'Per CDM: Response is required at this field. Please consider to update else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 11:29:57
User entered empty.	Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:15:03

US3572076

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:15:03

US3572076

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:15:03

US3572076

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User entered empty.	System	30 Aug 2020 15:15:03

US3572076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	24 Aug 2020 17:45:09

US3572076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	24 Aug 2020 17:45:09

US3572076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty.	(b) (4) Alisha Lutat (b) (4)	24 Aug 2020 17:45:09

US3572076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User entered 'MRNA-1273 OR PLACEBO'	System	24 Aug 2020 17:45:09

US3572076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '24 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	24 Aug 2020 17:45:09

US3572076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '12:31'	(b) (4) Alisha Lutat (b) (4) (b) (4)	24 Aug 2020 17:45:09

US3572076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User entered '24 Aug 2020 12:31'	System	24 Aug 2020 17:45:09

US3572076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Left Arm (LEFT ARM)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	24 Aug 2020 17:45:09

US3572076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User entered 'ONCE'	System	24 Aug 2020 17:45:09

US3572076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User entered 'INTRAMUSCULAR'	System	24 Aug 2020 17:45:09

US3572076

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:15:25

US3572076

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '24 Aug 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:15:25

US3572076

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '12:00'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:15:25

US3572076

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User entered '24 Aug 2020 12:00'	System	30 Aug 2020 15:15:25

US3572076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:17:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Nasopharyngeal Swab sample with a Collection date of 01SEP2020, however, per Viracor, the 01SEP2020 sample is recorded for Visit 1 Day 1. Please confirm the correct Visit Name in the query response, as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 06:09:30
Query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Nasopharyngeal Swab sample with a Collection date of 01SEP2020, however, per Viracor, the 01SEP2020 sample is recorded for Visit 1 Day 1. Please confirm the correct Visit Name in the query response, as appropriate. ' answered with '01SEP2020 was an unscheduled visit.' (Site from DM).	Caitlin roll (b) (4)	16 Feb 2021 17:23:19
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Nasopharyngeal Swab sample with a Collection date of 01SEP2020, however, per Viracor, the 01SEP2020 sample is recorded for Visit 1 Day 1. Please confirm the correct Visit Name in the query response, as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 17:37:46
User entered '24 Aug 2020'	Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:16:12

US3572076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:16:12

US3572076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:16:12

US3572076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '12:25'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:16:12

US3572076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User entered '24 Aug 2020 12:25'	System	30 Aug 2020 15:16:12

US3572076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:16:12

US3572076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:16:12

US3572076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:16:12

US3572076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User entered empty.	System	30 Aug 2020 15:16:12

US3572076

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:16:23

US3572076

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User entered 'I'	System	30 Aug 2020 15:16:23

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	24 Aug 2020 17:45:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-24T13:17:35', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '84a8f0b2-f492-43d5-bae7-70d5e1247068' User entered 'Yes (Y)'	System	24 Aug 2020 18:17:55
	System	24 Aug 2020 18:17:55

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-24T13:17:42', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '84a8f0b2-f492-43d5-bae7-70d5e1247068' User entered '98.1'	System	24 Aug 2020 18:17:55
	System	24 Aug 2020 18:17:55

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-24T13:17:46', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '84a8f0b2-f492-43d5-bae7-70d5e1247068'	System	24 Aug 2020 18:17:55
User entered 'No (N)'	System	24 Aug 2020 18:17:55

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-24T13:17:53', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '84a8f0b2-f492-43d5-bae7-70d5e1247068' User entered '24 Aug 2020 13:17'	System	24 Aug 2020 18:17:55
	System	24 Aug 2020 18:17:55

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '24 Aug 2020 12:51'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '24 Aug 2020 15:21'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	24 Aug 2020 17:45:09
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-25T11:06:02', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'c0474bac-bccc-46e5-9940-bc43a34c62dd' User entered 'Yes (Y)'	System	25 Aug 2020 16:06:14
	System	25 Aug 2020 16:06:14

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-25T11:06:06', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'c0474bac-bccc-46e5-9940-bc43a34c62dd' User entered '98.1'	System	25 Aug 2020 16:06:14
	System	25 Aug 2020 16:06:14

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-25T11:06:09', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'c0474bac-bccc-46e5-9940-bc43a34c62dd' User entered 'No (N)'	System	25 Aug 2020 16:06:14
	System	25 Aug 2020 16:06:14

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-25T11:06:11', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'c0474bac-bccc-46e5-9940-bc43a34c62dd' User entered '25 Aug 2020 11:06'	System	25 Aug 2020 16:06:14
	System	25 Aug 2020 16:06:14

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '24 Aug 2020 16:16'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	24 Aug 2020 17:45:09
User entered 'Day 2'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-26T10:13:58', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'dfec5d83-e5dc-403b-b4e5-26e6a18e0d09' User entered 'Yes (Y)'	System	26 Aug 2020 15:14:10
	System	26 Aug 2020 15:14:10

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-26T10:14:02', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'dfec5d83-e5dc-403b-b4e5-26e6a18e0d09' User entered '98.1'	System	26 Aug 2020 15:14:10
	System	26 Aug 2020 15:14:10

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-26T10:14:05', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'dfec5d83-e5dc-403b-b4e5-26e6a18e0d09'	System	26 Aug 2020 15:14:10
User entered 'No (N)'	System	26 Aug 2020 15:14:10

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-26T10:14:08', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'dfec5d83-e5dc-403b-b4e5-26e6a18e0d09'	System	26 Aug 2020 15:14:10
User entered '26 Aug 2020 10:14'	System	26 Aug 2020 15:14:10

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	24 Aug 2020 17:45:09
User entered 'Day 3'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-27T09:26:21', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '628a51db-5631-4213-a98e-b6ab6b619c4f' User entered 'Yes (Y)'	System	27 Aug 2020 14:26:36
	System	27 Aug 2020 14:26:36

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-27T09:26:26', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '628a51db-5631-4213-a98e-b6ab6b619c4f' User entered '98.1'	System	27 Aug 2020 14:26:36
	System	27 Aug 2020 14:26:36

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-27T09:26:29', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '628a51db-5631-4213-a98e-b6ab6b619c4f' User entered 'No (N)'	System	27 Aug 2020 14:26:36
	System	27 Aug 2020 14:26:36

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-27T09:26:31', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '628a51db-5631-4213-a98e-b6ab6b619c4f' User entered '27 Aug 2020 09:26'	System	27 Aug 2020 14:26:36
	System	27 Aug 2020 14:26:36

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	24 Aug 2020 17:45:09
User entered 'Day 4'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-28T10:08:34', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '7aedd1d7-878c-432b-ba76-9b1ffa3df22d' User entered 'Yes (Y)'	System	28 Aug 2020 15:08:42
	System	28 Aug 2020 15:08:42

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-28T10:08:37', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '7aedd1d7-878c-432b-ba76-9b1ffa3df22d' User entered '98.1'	System	28 Aug 2020 15:08:42
	System	28 Aug 2020 15:08:42

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-28T10:08:39', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '7aedd1d7-878c-432b-ba76-9b1ffa3df22d' User entered 'No (N)'	System	28 Aug 2020 15:08:42
	System	28 Aug 2020 15:08:42

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-28T10:08:41', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '7aedd1d7-878c-432b-ba76-9b1ffa3df22d' User entered '28 Aug 2020 10:08'	System	28 Aug 2020 15:08:42
	System	28 Aug 2020 15:08:42

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	24 Aug 2020 17:45:09
User entered 'Day 5'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-29T11:19:51', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '158aa834-e2d5-4199-938d-e260b3ef3bde' User entered 'Yes (Y)'	System	29 Aug 2020 16:20:05
	System	29 Aug 2020 16:20:05

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-29T11:19:56', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '158aa834-e2d5-4199-938d-e260b3ef3bde' User entered '98.1'	System	29 Aug 2020 16:20:05
	System	29 Aug 2020 16:20:05

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-29T11:19:58', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '158aa834-e2d5-4199-938d-e260b3ef3bde' User entered 'No (N)'	System	29 Aug 2020 16:20:05
	System	29 Aug 2020 16:20:05

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-29T11:20:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '158aa834-e2d5-4199-938d-e260b3ef3bde' User entered '29 Aug 2020 11:20'	System	29 Aug 2020 16:20:05
	System	29 Aug 2020 16:20:05

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	24 Aug 2020 17:45:09
User entered 'Day 6'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:25

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	24 Aug 2020 17:45:09
User entered 'Day 7'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-30T12:25:25', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '5a42a097-c1a5-4d4c-847e-e292b2b1224f' User entered 'Yes (Y)'	System	30 Aug 2020 17:25:37
	System	30 Aug 2020 17:25:37

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-30T12:25:28', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '5a42a097-c1a5-4d4c-847e-e292b2b1224f' User entered '98.1'	System	30 Aug 2020 17:25:37
	System	30 Aug 2020 17:25:37

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-30T12:25:31', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '5a42a097-c1a5-4d4c-847e-e292b2b1224f' User entered 'No (N)'	System	30 Aug 2020 17:25:37
	System	30 Aug 2020 17:25:37

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-30T12:25:34', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '5a42a097-c1a5-4d4c-847e-e292b2b1224f' User entered '30 Aug 2020 12:25'	System	30 Aug 2020 17:25:37
	System	30 Aug 2020 17:25:37

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
Data entry locked.	System	24 Aug 2020 17:45:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

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 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-24T13:18:27', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'b806dd4e-2e7c-4efc-8a6d-8a17e5960a08'	System	24 Aug 2020 18:18:41
User entered 'None (1)'	System	24 Aug 2020 18:18:41

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-24T13:18:29', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'b806dd4e-2e7c-4efc-8a6d-8a17e5960a08' User entered 'No (N)'	System	24 Aug 2020 18:18:41
	System	24 Aug 2020 18:18:41

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-24T13:18:32', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'b806dd4e-2e7c-4efc-8a6d-8a17e5960a08' User entered 'No (N)'	System	24 Aug 2020 18:18:41
	System	24 Aug 2020 18:18:41

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

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 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-24T13:18:36', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'b806dd4e-2e7c-4efc-8a6d-8a17e5960a08' User entered 'None (1)'	System	24 Aug 2020 18:18:41
	System	24 Aug 2020 18:18:41

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-24T13:18:38', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'b806dd4e-2e7c-4efc-8a6d-8a17e5960a08' User entered '24 Aug 2020 13:18'	System	24 Aug 2020 18:18:41
	System	24 Aug 2020 18:18:41

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '24 Aug 2020 12:51'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '24 Aug 2020 15:21'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
Data entry locked.	System	24 Aug 2020 17:45:09
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

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 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-25T11:06:35', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'c75dbc3e-c670-416b-acb0-4bb702042a4d' User entered 'None (1)'	System	25 Aug 2020 16:06:55
	System	25 Aug 2020 16:06:55

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-25T11:06:43', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'c75dbc3e-c670-416b-acb0-4bb702042a4d' User entered 'No (N)'	System	25 Aug 2020 16:06:55
	System	25 Aug 2020 16:06:55

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-25T11:06:47', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'c75dbc3e-c670-416b-acb0-4bb702042a4d' User entered 'No (N)'	System	25 Aug 2020 16:06:55
	System	25 Aug 2020 16:06:55

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

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 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-25T11:06:51', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'c75dbc3e-c670-416b-acb0-4bb702042a4d' User entered 'None (1)'	System	25 Aug 2020 16:06:55
	System	25 Aug 2020 16:06:55

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-25T11:06:53', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'c75dbc3e-c670-416b-acb0-4bb702042a4d' User entered '25 Aug 2020 11:06'	System	25 Aug 2020 16:06:55
	System	25 Aug 2020 16:06:55

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '24 Aug 2020 16:16'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
Data entry locked.	System	24 Aug 2020 17:45:09
User entered 'Day 2'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:25

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 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-26T10:14:21', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '9b973100-c482-4094-b56c-8ebbf934d295'	System	26 Aug 2020 15:14:37
User entered 'None (1)'	System	26 Aug 2020 15:14:37

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-26T10:14:23', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '9b973100-c482-4094-b56c-8ebbf934d295' User entered 'No (N)'	System	26 Aug 2020 15:14:37
	System	26 Aug 2020 15:14:37

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-26T10:14:27', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '9b973100-c482-4094-b56c-8ebbf934d295'	System	26 Aug 2020 15:14:37
User entered 'No (N)'	System	26 Aug 2020 15:14:37

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:25

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 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-26T10:14:32', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '9b973100-c482-4094-b56c-8ebbf934d295'	System	26 Aug 2020 15:14:37
User entered 'None (1)'	System	26 Aug 2020 15:14:37

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-26T10:14:34', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '9b973100-c482-4094-b56e-8ebbf934d295' User entered '26 Aug 2020 10:14'	System	26 Aug 2020 15:14:37
	System	26 Aug 2020 15:14:37

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
Data entry locked.	System	24 Aug 2020 17:45:09
User entered 'Day 3'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:25

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 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-27T09:26:34', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'f2c7d7ce-1ff4-4d82-bd05-3942e3ec2beb' User entered 'None (1)'	System	27 Aug 2020 14:26:49
	System	27 Aug 2020 14:26:49

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-27T09:26:37', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'f2c7d7ce-1ff4-4d82-bd05-3942e3ec2beb' User entered 'No (N)'	System	27 Aug 2020 14:26:49
	System	27 Aug 2020 14:26:49

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-27T09:26:38', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'f2c7d7ce-1ff4-4d82-bd05-3942e3ec2beb' User entered 'No (N)'	System	27 Aug 2020 14:26:49
	System	27 Aug 2020 14:26:49

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:25

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 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-27T09:26:43', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'f2c7d7ce-1ff4-4d82-bd05-3942e3ec2beb' User entered 'None (1)'	System	27 Aug 2020 14:26:49
	System	27 Aug 2020 14:26:49

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-27T09:26:46', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'f2c7d7ce-1ff4-4d82-bd05-3942e3ec2beb' User entered '27 Aug 2020 09:26'	System	27 Aug 2020 14:26:49
	System	27 Aug 2020 14:26:49

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
Data entry locked.	System	24 Aug 2020 17:45:09
User entered 'Day 4'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:25

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 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-28T10:08:44', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '3d3157bb-09e1-406c-952a-23a3da16a804' User entered 'None (1)'	System	28 Aug 2020 15:08:59
	System	28 Aug 2020 15:08:59

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-28T10:08:48', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '3d3157bb-09e1-406c-952a-23a3da16a804' User entered 'No (N)'	System	28 Aug 2020 15:08:59
	System	28 Aug 2020 15:08:59

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-28T10:08:51', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '3d3157bb-09e1-406c-952a-23a3da16a804' User entered 'No (N)'	System	28 Aug 2020 15:08:59
	System	28 Aug 2020 15:08:59

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:25

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 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-28T10:08:53', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '3d3157bb-09e1-406c-952a-23a3da16a804' User entered 'None (1)'	System	28 Aug 2020 15:08:59
	System	28 Aug 2020 15:08:59

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-28T10:08:55', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '3d3157bb-09e1-406c-952a-23a3da16a804' User entered '28 Aug 2020 10:08'	System	28 Aug 2020 15:08:59
	System	28 Aug 2020 15:08:59

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
Data entry locked.	System	24 Aug 2020 17:45:09
User entered 'Day 5'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:25

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 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-29T11:20:04', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '910771b1-c181-432e-b0b1-dfef0619faf5'	System	29 Aug 2020 16:20:16
User entered 'None (1)'	System	29 Aug 2020 16:20:16

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-29T11:20:06', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '910771b1-c181-432e-b0b1-dfef0619faf5' User entered 'No (N)'	System	29 Aug 2020 16:20:16
	System	29 Aug 2020 16:20:16

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-29T11:20:09', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '910771b1-c181-432e-b0b1-dfef0619faf5' User entered 'No (N)'	System	29 Aug 2020 16:20:16
	System	29 Aug 2020 16:20:16

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:25

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 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-29T11:20:13', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '910771b1-c181-432e-b0b1-dfef0619faf5'	System	29 Aug 2020 16:20:16
User entered 'None (1)'	System	29 Aug 2020 16:20:16

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-29T11:20:15', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '910771b1-c181-432e-b0b1-dfef0619faf5' User entered '29 Aug 2020 11:20'	System	29 Aug 2020 16:20:16
	System	29 Aug 2020 16:20:16

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
Data entry locked.	System	24 Aug 2020 17:45:09
User entered 'Day 6'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:25

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 02:48:48

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:25

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:25

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 02:48:48

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
Data entry locked.	System	24 Aug 2020 17:45:09
User entered 'Day 7'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:25

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 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-30T12:25:36', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '00471c02-009a-4203-baad-4b883f99d821' User entered 'None (1)'	System	30 Aug 2020 17:25:48
	System	30 Aug 2020 17:25:48

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-30T12:25:39', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '00471c02-009a-4203-baad-4b883f99d821' User entered 'No (N)'	System	30 Aug 2020 17:25:48
	System	30 Aug 2020 17:25:48

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-30T12:25:42', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '00471c02-009a-4203-baad-4b883f99d821' User entered 'No (N)'	System	30 Aug 2020 17:25:48
	System	30 Aug 2020 17:25:48

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:25

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 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-30T12:25:43', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '00471c02-009a-4203-baad-4b883f99d821'	System	30 Aug 2020 17:25:48
User entered 'None (1)'	System	30 Aug 2020 17:25:48

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-30T12:25:45', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '00471c02-009a-4203-baad-4b883f99d821' User entered '30 Aug 2020 12:25'	System	30 Aug 2020 17:25:48
	System	30 Aug 2020 17:25:48

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
Data entry locked.	System	24 Aug 2020 17:45:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-24T13:18:45', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'f8325274-7bda-4ad4-bf8c-92bc9a04c79a' User entered 'None (0)'	System	24 Aug 2020 18:54:06
	System	24 Aug 2020 18:54:06

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-24T13:18:52', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'f8325274-7bda-4ad4-bf8c-92bc9a04c79a'	System	24 Aug 2020 18:54:06
User entered 'No interference with activity (1)'	System	24 Aug 2020 18:54:06

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-24T13:18:57', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'f8325274-7bda-4ad4-bf8c-92bc9a04c79a'	System	24 Aug 2020 18:54:06
User entered 'No interference with activity (1)'	System	24 Aug 2020 18:54:06

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-24T13:18:59', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'f8325274-7bda-4ad4-bf8c-92bc9a04c79a'	System	24 Aug 2020 18:54:06
User entered 'No interference with activity (1)'	System	24 Aug 2020 18:54:06

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-24T13:53:49', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'f8325274-7bda-4ad4-bf8c-92bc9a04c79a'	System	24 Aug 2020 18:54:06
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	24 Aug 2020 18:54:06

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-24T13:53:52', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'f8325274-7bda-4ad4-bf8c-92bc9a04c79a'	System	24 Aug 2020 18:54:06
User entered 'No interference with activity (1)'	System	24 Aug 2020 18:54:06

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

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 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-24T13:54:01', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'f8325274-7bda-4ad4-bf8c-92bc9a04c79a' User entered 'No (N)'	System	24 Aug 2020 18:54:06
	System	24 Aug 2020 18:54:06

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-24T13:54:03', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'f8325274-7bda-4ad4-bf8c-92bc9a04c79a' User entered '24 Aug 2020 13:54'	System	24 Aug 2020 18:54:06
	System	24 Aug 2020 18:54:06

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '24 Aug 2020 12:51'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '24 Aug 2020 15:21'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
Data entry locked.	System	24 Aug 2020 17:45:09
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-25T11:06:57', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'bcc97ad-551d-40ec-bb93-f210ff85917d' User entered 'None (0)'	System	25 Aug 2020 16:07:53
	System	25 Aug 2020 16:07:53

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-25T11:07:29', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'bcca97ad-551d-40ec-bb93-f210ff85917d'	System	25 Aug 2020 16:07:53
User entered 'No interference with activity (1)'	System	25 Aug 2020 16:07:53

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-25T11:07:32', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'bcc97ad-551d-40ec-bb93-f210ff85917d'	System	25 Aug 2020 16:07:53
User entered 'No interference with activity (1)'	System	25 Aug 2020 16:07:53

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-25T11:07:34', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'bcc97ad-551d-40ec-bb93-f210ff85917d'	System	25 Aug 2020 16:07:53
User entered 'No interference with activity (1)'	System	25 Aug 2020 16:07:53

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-25T11:07:38', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'bcc97ad-551d-40ec-bb93-f210ff85917d'	System	25 Aug 2020 16:07:53
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	25 Aug 2020 16:07:53

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-25T11:07:41', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'bcc97ad-551d-40ec-bb93-f210ff85917d'	System	25 Aug 2020 16:07:53
User entered 'Some interference with activity not requiring medical attention (2)'	System	25 Aug 2020 16:07:53

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

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 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-25T11:07:47', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'bcc97ad-551d-40ec-bb93-f210ff85917d' User entered 'No (N)'	System	25 Aug 2020 16:07:53
	System	25 Aug 2020 16:07:53

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-25T11:07:50', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'bcca97ad-551d-40ec-bb93-f210ff85917d' User entered '25 Aug 2020 11:07'	System	25 Aug 2020 16:07:53
	System	25 Aug 2020 16:07:53

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '24 Aug 2020 16:16'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
Data entry locked.	System	24 Aug 2020 17:45:09
User entered 'Day 2'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-26T10:14:55', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'ab563b82-ccaa-4889-bcad-66f6a9aa5b73' User entered 'None (0)'	System	26 Aug 2020 15:15:14
	System	26 Aug 2020 15:15:14

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-26T10:14:58', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'ab563b82-ccaa-4889-bcad-66f6a9aa5b73' User entered 'None (0)'	System	26 Aug 2020 15:15:14
	System	26 Aug 2020 15:15:14

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-26T10:15:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'ab563b82-ccaa-4889-bcad-66f6a9aa5b73'	System	26 Aug 2020 15:15:14
User entered 'No interference with activity (1)'	System	26 Aug 2020 15:15:14

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-26T10:15:02', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'ab563b82-ccaa-4889-bcad-66f6a9aa5b73' User entered 'None (0)'	System	26 Aug 2020 15:15:14
	System	26 Aug 2020 15:15:14

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-26T10:15:04', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'ab563b82-ccaa-4889-bcad-66f6a9aa5b73' User entered 'None (0)'	System	26 Aug 2020 15:15:14
	System	26 Aug 2020 15:15:14

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-26T10:15:06', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'ab563b82-ccaa-4889-bcad-66f6a9aa5b73' User entered 'None (0)'	System	26 Aug 2020 15:15:14
	System	26 Aug 2020 15:15:14

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:25

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 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-26T10:15:08', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'ab563b82-ccaa-4889-bcad-66f6a9aa5b73' User entered 'No (N)'	System	26 Aug 2020 15:15:14
	System	26 Aug 2020 15:15:14

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-26T10:15:10', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'ab563b82-ccaa-4889-bcad-66f6a9aa5b73' User entered '26 Aug 2020 10:15'	System	26 Aug 2020 15:15:14
	System	26 Aug 2020 15:15:14

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
Data entry locked.	System	24 Aug 2020 17:45:09
User entered 'Day 3'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-27T09:35:13', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '5a0909a3-8577-4a55-b7c5-6029e3900ada' User entered 'None (0)'	System	27 Aug 2020 14:35:59
	System	27 Aug 2020 14:35:59

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-27T09:35:19', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '5a0909a3-8577-4a55-b7c5-6029e3900ada' User entered 'No interference with activity (1)'	System	27 Aug 2020 14:35:59
	System	27 Aug 2020 14:35:59

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-27T09:35:22', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '5a0909a3-8577-4a55-b7c5-6029e3900ada' User entered 'No interference with activity (1)'	System	27 Aug 2020 14:35:59
	System	27 Aug 2020 14:35:59

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-27T09:35:24', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '5a0909a3-8577-4a55-b7c5-6029e3900ada' User entered 'No interference with activity (1)'	System	27 Aug 2020 14:35:59
	System	27 Aug 2020 14:35:59

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-27T09:35:47', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '5a0909a3-8577-4a55-b7c5-6029e3900ada'	System	27 Aug 2020 14:35:59
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	27 Aug 2020 14:35:59

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-27T09:35:49', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '5a0909a3-8577-4a55-b7c5-6029e3900ada' User entered 'No interference with activity (1)'	System	27 Aug 2020 14:35:59
	System	27 Aug 2020 14:35:59

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:25

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 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-27T09:35:51', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '5a0909a3-8577-4a55-b7c5-6029e3900ada' User entered 'No (N)'	System	27 Aug 2020 14:35:59
	System	27 Aug 2020 14:35:59

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-27T09:35:54', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '5a0909a3-8577-4a55-b7c5-6029e3900ada' User entered '27 Aug 2020 09:35'	System	27 Aug 2020 14:35:59
	System	27 Aug 2020 14:35:59

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
Data entry locked.	System	24 Aug 2020 17:45:09
User entered 'Day 4'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-28T10:08:58', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'a7d2d420-19af-4822-bbfa-089c415025d5' User entered 'None (0)'	System	28 Aug 2020 15:09:13
	System	28 Aug 2020 15:09:13

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-28T10:09:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'a7d2d420-19af-4822-bbfa-089c415025d5' User entered 'None (0)'	System	28 Aug 2020 15:09:13
	System	28 Aug 2020 15:09:13

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-28T10:09:02', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'a7d2d420-19af-4822-bbfa-089c415025d5' User entered 'None (0)'	System	28 Aug 2020 15:09:13
	System	28 Aug 2020 15:09:13

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-28T10:09:04', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'a7d2d420-19af-4822-bbfa-089c415025d5' User entered 'None (0)'	System	28 Aug 2020 15:09:13
	System	28 Aug 2020 15:09:13

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-28T10:09:05', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'a7d2d420-19af-4822-bbfa-089c415025d5' User entered 'None (0)'	System	28 Aug 2020 15:09:13
	System	28 Aug 2020 15:09:13

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-28T10:09:07', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'a7d2d420-19af-4822-bbfa-089c415025d5' User entered 'None (0)'	System	28 Aug 2020 15:09:13
	System	28 Aug 2020 15:09:13

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:25

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 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-28T10:09:09', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'a7d2d420-19af-4822-bbfa-089c415025d5' User entered 'No (N)'	System	28 Aug 2020 15:09:13
	System	28 Aug 2020 15:09:13

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-28T10:09:11', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'a7d2d420-19af-4822-bbfa-089c415025d5' User entered '28 Aug 2020 10:09'	System	28 Aug 2020 15:09:13
	System	28 Aug 2020 15:09:13

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
Data entry locked.	System	24 Aug 2020 17:45:09
User entered 'Day 5'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-29T11:20:18', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '3c2c16ae-ab0c-4fcf-b480-c9f56628e085' User entered 'None (0)'	System	29 Aug 2020 16:20:32
	System	29 Aug 2020 16:20:32

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-29T11:20:19', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '3c2c16ae-ab0c-4fcf-b480-c9f56628e085' User entered 'None (0)'	System	29 Aug 2020 16:20:32
	System	29 Aug 2020 16:20:32

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-29T11:20:20', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '3c2c16ae-ab0c-4fcf-b480-c9f56628e085' User entered 'None (0)'	System	29 Aug 2020 16:20:32
	System	29 Aug 2020 16:20:32

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-29T11:20:22', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '3c2c16ae-ab0c-4fcf-b480-c9f56628e085' User entered 'None (0)'	System	29 Aug 2020 16:20:32
	System	29 Aug 2020 16:20:32

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-29T11:20:24', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '3c2c16ae-ab0c-4fcf-b480-c9f56628e085' User entered 'None (0)'	System	29 Aug 2020 16:20:32
	System	29 Aug 2020 16:20:32

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-29T11:20:26', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '3c2c16ae-ab0c-4fcf-b480-c9f56628e085' User entered 'None (0)'	System	29 Aug 2020 16:20:32
	System	29 Aug 2020 16:20:32

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:25

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 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-29T11:20:28', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '3c2c16ae-ab0c-4fcf-b480-c9f56628e085' User entered 'No (N)'	System	29 Aug 2020 16:20:32
	System	29 Aug 2020 16:20:32

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-29T11:20:30', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '3c2c16ae-ab0c-4fcf-b480-c9f56628e085' User entered '29 Aug 2020 11:20'	System	29 Aug 2020 16:20:32
	System	29 Aug 2020 16:20:32

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
Data entry locked.	System	24 Aug 2020 17:45:09
User entered 'Day 6'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:25

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 02:48:48

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
Data entry locked.	System	24 Aug 2020 17:45:09
User entered 'Day 7'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-30T12:25:47', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '56234c7a-457f-4748-ab79-d5a780f155e8' User entered 'None (0)'	System	30 Aug 2020 17:26:00
	System	30 Aug 2020 17:26:00

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-30T12:25:48', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '56234c7a-457f-4748-ab79-d5a780f155e8' User entered 'No interference with activity (1)'	System	30 Aug 2020 17:26:00
	System	30 Aug 2020 17:26:00

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-30T12:25:49', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '56234c7a-457f-4748-ab79-d5a780f155e8' User entered 'No interference with activity (1)'	System	30 Aug 2020 17:26:00
	System	30 Aug 2020 17:26:00

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-30T12:25:51', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '56234c7a-457f-4748-ab79-d5a780f155e8' User entered 'None (0)'	System	30 Aug 2020 17:26:00
	System	30 Aug 2020 17:26:00

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-30T12:25:52', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '56234c7a-457f-4748-ab79-d5a780f155e8' User entered 'None (0)'	System	30 Aug 2020 17:26:00
	System	30 Aug 2020 17:26:00

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-30T12:25:54', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '56234c7a-457f-4748-ab79-d5a780f155e8' User entered 'None (0)'	System	30 Aug 2020 17:26:00
	System	30 Aug 2020 17:26:00

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:25

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 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-30T12:25:55', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '56234c7a-457f-4748-ab79-d5a780f155e8' User entered 'No (N)'	System	30 Aug 2020 17:26:00
	System	30 Aug 2020 17:26:00

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-30T12:25:57', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '56234c7a-457f-4748-ab79-d5a780f155e8' User entered '30 Aug 2020 12:25'	System	30 Aug 2020 17:26:00
	System	30 Aug 2020 17:26:00

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 17:45:09

US3572076

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
Data entry locked.	System	30 Aug 2020 17:26:00
User entered 'Day 8'	System	30 Aug 2020 17:26:00

US3572076

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:17:25

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-31T13:35:58', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '91f42370-acbe-42b0-bb00-7eaf5c48c6ee' User entered 'None (0)'	System	31 Aug 2020 18:36:05
	System	31 Aug 2020 18:36:05

US3572076

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-31T13:36:03', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '91f42370-acbe-42b0-bb00-7eaf5c48c6ee' User entered '31 Aug 2020 13:36'	System	31 Aug 2020 18:36:05
	System	31 Aug 2020 18:36:05

US3572076

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 17:26:00

US3572076

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 17:26:00

US3572076

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	30 Aug 2020 17:26:00
User entered 'Day 8'	System	30 Aug 2020 17:26:00

US3572076

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:17:25

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-31T13:36:07', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '54ce42ec-575c-46ca-8d10-310bd85bdbe2' User entered 'None (0)'	System	31 Aug 2020 18:36:14
	System	31 Aug 2020 18:36:14

US3572076

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:17:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-31T13:36:11', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '54ce42ec-575c-46ca-8d10-310bd85bdbbe2' User entered '31 Aug 2020 13:36'	System	31 Aug 2020 18:36:14
	System	31 Aug 2020 18:36:14

US3572076

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 17:26:00

US3572076

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 17:26:00

US3572076

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
Data entry locked.	System	30 Aug 2020 17:26:00
User entered 'Day 8'	System	30 Aug 2020 17:26:00

US3572076

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:17:25

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 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-31T13:36:17', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'c7efd1be-8e90-4161-a148-87bc8adf0497'	System	31 Aug 2020 18:36:24
User entered 'No (N)'	System	31 Aug 2020 18:36:24

US3572076

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:17:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-08-31T13:36:20', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'c7efd1be-8e90-4161-a148-87bc8adf0497' User entered '31 Aug 2020 13:36'	System	31 Aug 2020 18:36:24
	System	31 Aug 2020 18:36:24

US3572076

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 17:26:00

US3572076

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:48
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 17:26:00

US3572076

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:18:59

US3572076

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User closed query 'Per GCL Lab Reconciliation: Swab: Per response, "Sample collected on 01Sep2020 was for an Unscheduled Visit that has been reported in the EDC."; however, swab sample for 01-SEP-2020 is missing in EDC & in PPD portal it is present under unscheduled visit with accession number "1F621022250". Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for 01-SEP-2020 and updating swab data in Covid Diagnostic Test eCRF, as there is no provision to capture swab data in unscheduled eCRF, else clarify.' (Site from DM).	(b) (4) (u) (4), (b) (6)	15 Mar 2021 11:11:10
Query 'Per GCL Lab Reconciliation: Swab: Per response, "Sample collected on 01Sep2020 was for an Unscheduled Visit that has been reported in the EDC."; however, swab sample for 01-SEP-2020 is missing in EDC & in PPD portal it is present under unscheduled visit with accession number "1F621022250". Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for 01-SEP-2020 and updating swab data in Covid Diagnostic Test eCRF, as there is no provision to capture swab data in unscheduled eCRF, else clarify.' answered with 'Saliva sample collected for Illness D1' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 00:03:05

US3572076

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Swab: Per response, "Sample collected on 01Sep2020 was for an Unscheduled Visit that has been reported in the EDC."; however, swab sample for 01-SEP-2020 is missing in EDC & in PPD portal it is present under unscheduled visit with accession number "1F621022250". Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for 01-SEP-2020 and updating swab data in Covid Diagnostic Test eCRF, as there is no provision to capture swab data in unscheduled eCRF, else clarify.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 11:26:56
User closed query 'Per GCL Lab reconciliation re-query: SWAB: Please complete the covid diagnostic test for sample collected on 01Sep2020. As for the SARS-CoV-2 sample please complete an illness visit by adding the page from the add event drop down.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 11:26:56
Query 'Per GCL Lab reconciliation re-query: SWAB: Please complete the covid diagnostic test for sample collected on 01Sep2020. As for the SARS-CoV-2 sample please complete an illness visit by adding the page from the add event drop down.' answered with 'Sample collected on 01Sep2020 was for an Unscheduled Visit that has been reported in the EDC.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 04:04:41
User opened query 'Per GCL Lab reconciliation re-query: SWAB: Please complete the covid diagnostic test for sample collected on 01Sep2020. As for the SARS-CoV-2 sample please complete an illness visit by adding the page from the add event drop down.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 13:09:35
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled COVID PCR Swab sample, COVID PCR Saliva sample, and SARS-CoV-2 Serum sample with a Collection date of 01SEP2020, however these samples are not presently recorded in the CRF. Please clarify if an Unscheduled visit should be added for the subject and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 13:09:35

US3572076

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation Requery: Antibody-mediated Immunogenicity: Thank you for the response please update the data under UNSCHEDULE visit.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 10:47:26
Query 'Per GCL Lab Reconciliation Requery: Antibody-mediated Immunogenicity: Thank you for the response please update the data under UNSCHEDULE visit.' answered with 'Unscheduled visit added' (Site from DM).	Alisha Lutat (b) (4) (b) (4)	06 Nov 2020 18:24:17
User opened query 'Per GCL Lab Reconciliation Requery: Antibody-mediated Immunogenicity: Thank you for the response please update the data under UNSCHEDULE visit.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 12:55:17
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 01SEP2020, however this date is not presently recorded in the CRF. Please clarify if an Unscheduled visit should be added for the subject and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 12:55:17
Query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled COVID PCR Swab sample, COVID PCR Saliva sample, and SARS-CoV-2 Serum sample with a Collection date of 01SEP2020, however these samples are not presently recorded in the CRF. Please clarify if an Unscheduled visit should be added for the subject and update as appropriate. ' answered with 'Please advise how to add UNS visit. Confirmed pt was seen on 9/1/2020. ' (Site from DM).	Alisha Lutat (b) (4) (b) (4)	28 Oct 2020 20:41:58
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled COVID PCR Swab sample, COVID PCR Saliva sample, and SARS-CoV-2 Serum sample with a Collection date of 01SEP2020, however these samples are not presently recorded in the CRF. Please clarify if an Unscheduled visit should be added for the subject and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 15:03:59

US3572076

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled COVID PCR Swab sample, COVID PCR Saliva sample, and SARS CoV2 Serum sample with a Collection date of 01SEP2020, however these samples are not presently recorded in the CRF. Please clarify if an Unscheduled visit should be added for the subject and update as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 15:03:54
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled COVID PCR Swab sample, COVID PCR Saliva sample, and SARS CoV2 Serum sample with a Collection date of 01SEP2020, however these samples are not presently recorded in the CRF. Please clarify if an Unscheduled visit should be added for the subject and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 15:00:07
Query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 01SEP2020, however this date is not presently recorded in the CRF. Please clarify if an Unscheduled visit should be added for the subject and update as appropriate.' answered with 'Unscheduled Immunogenicity was collected 03 Sep 2020. Please advise where to document this date in EDC ' (Site from DM).	Alisha Lutat (b) (4) (b) (4)	26 Oct 2020 01:03:12
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 01SEP2020, however this date is not presently recorded in the CRF. Please clarify if an Unscheduled visit should be added for the subject and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 15:09:01
User entered '31 Aug 2020'	Jasmine Ali (b) (4) (b) (4)	31 Aug 2020 20:18:59

US3572076

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:18:59

US3572076

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:18:59

US3572076

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Jasmine Ali (b) (4)	08 Sep 2020 19:05:46

US3572076

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered 'I'	System	08 Sep 2020 19:05:46

US3572076

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Jasmine Ali (b) (4)	08 Sep 2020 19:15:25

US3572076

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User closed query 'Per GCL Reconciliation: Saliva sample collected on 01SEP2020 is labelled under "Illness D1" in Viracor data and in GCL it is labelled under "Unscheduled". Please verify the correct visit for sample collected on this date.' (Site from DM).	(b) (4)	23 Nov 2020 11:42:52
Query 'Per GCL Reconciliation: Saliva sample collected on 01SEP2020 is labelled under "Illness D1" in Viracor data and in GCL it is labelled under "Unscheduled". Please verify the correct visit for sample collected on this date.' answered with 'Saliva sample collected on 01 sep2020 was for Unscheduled Visit ' (Site from DM).	(u) (4), (b) (6)	
Query 'Per GCL Reconciliation: Saliva sample collected on 01SEP2020 is labelled under "Illness D1" in Viracor data and in GCL it is labelled under "Unscheduled". Please verify the correct visit for sample collected on this date.' answered with 'Saliva sample collected on 01 sep2020 was for Unscheduled Visit ' (Site from DM).	Alisha Lutat (b) (4)	05 Nov 2020 18:29:43
User opened query 'Per GCL Reconciliation: Saliva sample collected on 01SEP2020 is labelled under "Illness D1" in Viracor data and in GCL it is labelled under "Unscheduled". Please verify the correct visit for sample collected on this date.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 07:47:37
User entered '9 Sep 2020' reason for change: New Information	Jasmine Ali (b) (4)	09 Sep 2020 15:37:56
User entered '8 Sep 2020'	(b) (4)	
	Jasmine Ali (b) (4)	08 Sep 2020 19:15:25
	(b) (4)	

US3572076

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: New Information	Jasmine Ali (b) (4)	09 Sep 2020 15:37:56
	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	Jasmine Ali (b) (4)	08 Sep 2020 19:15:25
	(b) (4)	

US3572076

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'voicemail box not set up. Text message sent to determine availability of patient'	(b) (4) Jasmine Ali (b) (4)	08 Sep 2020 19:15:25

US3572076

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Jasmine Ali (b) (4)	09 Sep 2020 15:38:01

US3572076

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:21
User entered 'l'	System	09 Sep 2020 15:38:01

US3572076

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22SEP2020 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 12:53:54
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22SEP2020 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)	22 Oct 2020 21:35:26
' answered with 'data updated' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22SEP2020 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 05:22:25
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	14 Sep 2020 14:56:35

US3572076

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '14 Sep 2020'	(b) (4) Jasmine Ali (b) (4) (b) (4)	14 Sep 2020 14:56:35

US3572076

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: New Information	Jasmine Ali (b) (4)	14 Sep 2020 19:29:44
	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	Jasmine Ali (b) (4)	14 Sep 2020 14:56:35
	(b) (4)	

US3572076

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'voicemail box not set up. text message sent to determine availability'	(b) (4) Jasmine Ali (b) (4)	14 Sep 2020 14:56:35

US3572076

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Jasmine Ali (b) (4)	14 Sep 2020 19:29:49

US3572076

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:21
User entered 'l'	System	14 Sep 2020 19:29:49

US3572076

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:28:54

US3572076

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '22 Sep 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:28:54

US3572076

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Clinic (Clinic)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:28:54

US3572076

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered 'VISIT2'	System	22 Oct 2020 21:28:54

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User accepted default value 'Pre-Dose (PREDOSE)'	Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '22 Sep 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '11:25'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered '22 Sep 2020 11:25'	System	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '98.7' F	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Other (Other)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'temporal'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '78'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered 'bpm'	System	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '18'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered 'breaths/min'	System	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '111'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered 'mmHg'	System	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '72'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered 'mmHg'	System	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User accepted default value 'Post-Dose (POSTDOSE)'	Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '22 Sep 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '12:43'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered '22 Sep 2020 12:43'	System	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '97.9' F	(b) (4) Alisha Lutat (b) (4)	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Other (Other)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'temporal'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '73'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered 'bpm'	System	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '18'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered 'breaths/min'	System	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '107'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered 'mmHg'	System	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '65'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered 'mmHg'	System	22 Oct 2020 21:30:38

US3572076

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:30:51

US3572076

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '22 Sep 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:30:51

US3572076

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:32:35

US3572076

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '22 Sep 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:32:35

US3572076

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Urine (URINE)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:32:35

US3572076

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Negative (NEGATIVE)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:32:35

US3572076

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:32:35

US3572076

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:32:35

US3572076

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:32:35

US3572076

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered empty.	System	22 Oct 2020 21:32:35

US3572076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 22SEP2020 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) (u) (4), (b) (6)	03 Nov 2020 11:20:56
Query 'Per GCL Lab Recon: GCL has immunogenicity sample with date of 22 sep 20however, sample (or visit) is not recorded in EDC. Please review and reconcile' canceled (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 19:17:16
User opened query 'Per GCL Lab Recon: GCL has immunogenicity sample with date of 22 sep 20however, sample (or visit) is not recorded in EDC. Please review and reconcile' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 19:16:54
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 22SEP2020 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 updated' (Site from DM).	Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:36:14
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 22SEP2020 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 07:29:19
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	22 Sep 2020 17:48:44

US3572076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Sep 2020 17:48:44

US3572076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

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)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Sep 2020 17:48:44

US3572076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered 'MRNA-1273 OR PLACEBO'	System	22 Sep 2020 17:48:44

US3572076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '22 Sep 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Sep 2020 17:48:44

US3572076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '12:13'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Sep 2020 17:48:44

US3572076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered '22 Sep 2020 12:13'	System	22 Sep 2020 17:48:44

US3572076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Left Arm (LEFT ARM)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Sep 2020 17:48:44

US3572076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered 'ONCE'	System	22 Sep 2020 17:48:44

US3572076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered 'INTRAMUSCULAR'	System	22 Sep 2020 17:48:44

US3572076

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:33:20

US3572076

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '22 Sep 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:33:20

US3572076

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '11:28'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:33:20

US3572076

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered '22 Sep 2020 11:28'	System	22 Oct 2020 21:33:20

US3572076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:17:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '22 Sep 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:33:56

US3572076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:33:56

US3572076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:33:56

US3572076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '10:58'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:33:56

US3572076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered '22 Sep 2020 10:58'	System	22 Oct 2020 21:33:56

US3572076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:33:56

US3572076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:33:56

US3572076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:33:56

US3572076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered empty.	System	22 Oct 2020 21:33:56

US3572076

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User closed query 'Per GCL Lab Reconciliation Requery 1: Please verify the visit for Saliva sample dated 01SEP2020, It is under Illness or Convalescence visit.Thanks' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 08:56:32
Query 'Per GCL Lab Reconciliation Requery 1: Please verify the visit for Saliva sample dated 01SEP2020, It is under Illness or Convalescence visit.Thanks' answered with 'As per query, information has been recorded under "Illness Visit" eCRF.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 19:56:01
User opened query 'Per GCL Lab Reconciliation Requery 1: Please verify the visit for Saliva sample dated 01SEP2020, It is under Illness or Convalescence visit.Thanks' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 09:19:58
User closed query 'Per GCL Lab Recon: it appears GCL has a Saliva Sample with date 01SEP2020 ; however there is no record in EDC. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 09:19:58
Query 'Per GCL Lab Recon: it appears GCL has a Saliva Sample with date 01SEP2020 ; however there is no record in EDC. Please reconcile or clarify.' answered with 'please advise where the saliva sample should be entered in EDC. ' (Site from DM).	Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:44:21
User opened query 'Per GCL Lab Recon: it appears GCL has a Saliva Sample with date 01SEP2020 ; however there is no record in EDC. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 11:49:33
User entered 'Yes (Y)'	Jackie Ziegler (b) (4) (b) (4)	02 Oct 2020 00:10:52

US3572076

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered 'I'	System	02 Oct 2020 00:10:52

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	22 Sep 2020 17:48:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T12:50:02', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'fc3f923d-1e0d-4121-9926-a2489b705c6c' User entered 'Yes (Y)'	System	22 Sep 2020 17:50:15
	System	22 Sep 2020 17:50:15

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T12:50:07', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'fc3f923d-1e0d-4121-9926-a2489b705c6c' User entered '97.9'	System	22 Sep 2020 17:50:15
	System	22 Sep 2020 17:50:15

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T12:50:09', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'fc3f923d-1e0d-4121-9926-a2489b705c6c' User entered 'No (N)'	System	22 Sep 2020 17:50:15
	System	22 Sep 2020 17:50:15

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T12:50:13', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'fc3f923d-1e0d-4121-9926-a2489b705c6c' User entered '22 Sep 2020 12:50'	System	22 Sep 2020 17:50:15
	System	22 Sep 2020 17:50:15

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '22 Sep 2020 12:33'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '22 Sep 2020 15:03'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	22 Sep 2020 17:48:44
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T23:58:51', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '2898d827-ae9a-41eb-8e8f-49c96ca27d1a' User entered 'Yes (Y)'	System	23 Sep 2020 04:59:03
	System	23 Sep 2020 04:59:03

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T23:58:56', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '2898d827-ae9a-41eb-8e8f-49c96ca27d1a' User entered '98.1'	System	23 Sep 2020 04:59:03
	System	23 Sep 2020 04:59:03

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T23:58:59', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '2898d827-ae9a-41eb-8e8f-49c96ca27d1a' User entered 'No (N)'	System	23 Sep 2020 04:59:03
	System	23 Sep 2020 04:59:03

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T23:59:01', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '2898d827-ae9a-41eb-8e8f-49c96ca27d1a' User entered '22 Sep 2020 23:59'	System	23 Sep 2020 04:59:03
	System	23 Sep 2020 04:59:03

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '22 Sep 2020 15:58'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	22 Sep 2020 17:48:44
User entered 'Day 2'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-23T16:47:33', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '7a0f052c-c6e5-4ff6-bdb5-cca8cc9ffac8'	System	23 Sep 2020 21:47:47
User entered 'Yes (Y)'	System	23 Sep 2020 21:47:47

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-23T16:47:37', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '7a0f052c-c6e5-4ff6-bdb5-cea8cc9ffac8' User entered '97.1'	System	23 Sep 2020 21:47:47
	System	23 Sep 2020 21:47:47

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-23T16:47:44', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '7a0f052c-c6e5-4ff6-bdb5-cca8cc9ffac8'	System	23 Sep 2020 21:47:47
User entered 'No (N)'	System	23 Sep 2020 21:47:47

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-23T16:47:46', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '7a0f052c-c6e5-4ff6-bdb5-cea8cc9ffac8' User entered '23 Sep 2020 16:47'	System	23 Sep 2020 21:47:47
	System	23 Sep 2020 21:47:47

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	22 Sep 2020 17:48:44
User entered 'Day 3'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-24T15:14:53', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'bb86d418-9f40-4776-8b23-37ab6d73cff0' User entered 'Yes (Y)'	System	24 Sep 2020 20:15:05
	System	24 Sep 2020 20:15:05

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-24T15:14:57', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'bb86d418-9f40-4776-8b23-37ab6d73cff0' User entered '97.1'	System	24 Sep 2020 20:15:05
	System	24 Sep 2020 20:15:05

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-24T15:15:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'bb86d418-9f40-4776-8b23-37ab6d73cff0'	System	24 Sep 2020 20:15:05
User entered 'No (N)'	System	24 Sep 2020 20:15:05

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-24T15:15:02', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'bb86d418-9f40-4776-8b23-37ab6d73cff0'	System	24 Sep 2020 20:15:05
User entered '24 Sep 2020 15:15'	System	24 Sep 2020 20:15:05

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	22 Sep 2020 17:48:44
User entered 'Day 4'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-25T23:59:15', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'e59ca305-04b9-4edf-996f-445a1232e201'	System	26 Sep 2020 04:59:24
User entered 'Yes (Y)'	System	26 Sep 2020 04:59:24

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-25T23:59:17', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'e59ca305-04b9-4edf-996f-445a1232e201' User entered '97.1'	System	26 Sep 2020 04:59:24
	System	26 Sep 2020 04:59:24

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-25T23:59:19', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'e59ca305-04b9-4edf-996f-445a1232e201' User entered 'No (N)'	System	26 Sep 2020 04:59:24
	System	26 Sep 2020 04:59:24

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-25T23:59:21', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'e59ca305-04b9-4edf-996f-445a1232e201'	System	26 Sep 2020 04:59:24
User entered '25 Sep 2020 23:59'	System	26 Sep 2020 04:59:24

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	22 Sep 2020 17:48:44
User entered 'Day 5'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-26T13:57:44', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'b1d21241-809f-40df-b9f5-b19fee88079a' User entered 'Yes (Y)'	System	26 Sep 2020 18:58:01
	System	26 Sep 2020 18:58:01

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-26T13:57:47', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'b1d21241-809f-40df-b9f5-b19fee88079a' User entered '98.1'	System	26 Sep 2020 18:58:01
	System	26 Sep 2020 18:58:01

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-26T13:57:57', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'b1d21241-809f-40df-b9f5-b19fee88079a' User entered 'No (N)'	System	26 Sep 2020 18:58:01
	System	26 Sep 2020 18:58:01

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-26T13:57:59', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'b1d21241-809f-40df-b9f5-b19fee88079a' User entered '26 Sep 2020 13:57'	System	26 Sep 2020 18:58:01
	System	26 Sep 2020 18:58:01

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	22 Sep 2020 17:48:44
User entered 'Day 6'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-27T20:23:05', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'e84dc31d-8454-4fc5-99fd-507bbaa3b4c7' User entered 'Yes (Y)'	System	28 Sep 2020 01:23:15
	System	28 Sep 2020 01:23:15

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-27T20:23:08', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'e84dc31d-8454-4fc5-99fd-507bbaa3b4c7' User entered '98.1'	System	28 Sep 2020 01:23:15
	System	28 Sep 2020 01:23:15

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-27T20:23:10', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'e84dc31d-8454-4fc5-99fd-507bbaa3b4c7' User entered 'No (N)'	System	28 Sep 2020 01:23:15
	System	28 Sep 2020 01:23:15

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-27T20:23:12', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'e84dc31d-8454-4fc5-99fd-507bbaa3b4c7' User entered '27 Sep 2020 20:23'	System	28 Sep 2020 01:23:15
	System	28 Sep 2020 01:23:15

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	22 Sep 2020 17:48:44
User entered 'Day 7'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-29T00:47:20', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '1fe6727d-434a-49ef-8441-b33ea3d4c496' User entered 'Yes (Y)'	System	29 Sep 2020 05:47:29
	System	29 Sep 2020 05:47:29

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-29T00:47:23', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '1fe6727d-434a-49ef-8441-b33ea3d4c496' User entered '98.1'	System	29 Sep 2020 05:47:29
	System	29 Sep 2020 05:47:29

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-29T00:47:24', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '1fe6727d-434a-49ef-8441-b33ea3d4c496' User entered 'No (N)'	System	29 Sep 2020 05:47:29
	System	29 Sep 2020 05:47:29

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-29T00:47:27', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '1fe6727d-434a-49ef-8441-b33ea3d4c496' User entered '29 Sep 2020 00:47'	System	29 Sep 2020 05:47:29
	System	29 Sep 2020 05:47:29

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	22 Sep 2020 17:48:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

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 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T12:50:18', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '3c1f8aac-531b-474d-9dff-b8b39d2cff84'	System	22 Sep 2020 17:50:43
User entered 'Does not interfere with activity (2)'	System	22 Sep 2020 17:50:43

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T12:50:32', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '3c1f8aac-531b-474d-9dff-b8b39d2cff84'	System	22 Sep 2020 17:50:43
User entered 'No (N)'	System	22 Sep 2020 17:50:43

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T12:50:35', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '3c1f8aac-531b-474d-9dff-b8b39d2cff84'	System	22 Sep 2020 17:50:43
User entered 'No (N)'	System	22 Sep 2020 17:50:43

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

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 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T12:50:39', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '3c1f8aac-531b-474d-9dff-b8b39d2cff84'	System	22 Sep 2020 17:50:43
User entered 'None (1)'	System	22 Sep 2020 17:50:43

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T12:50:41', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '3c1f8aac-531b-474d-9dff-b8b39d2cff84'	System	22 Sep 2020 17:50:43
User entered '22 Sep 2020 12:50'	System	22 Sep 2020 17:50:43

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '22 Sep 2020 12:33'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '22 Sep 2020 15:03'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	22 Sep 2020 17:48:44
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

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 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T23:59:07', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '61db9c97-b127-476f-ac03-3b66974be855'	System	23 Sep 2020 04:59:29
User entered 'None (1)'	System	23 Sep 2020 04:59:29

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T23:59:21', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '61db9c97-b127-476f-ac03-3b66974be855' User entered 'No (N)'	System	23 Sep 2020 04:59:29
	System	23 Sep 2020 04:59:29

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T23:59:23', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '61db9c97-b127-476f-ac03-3b66974be855' User entered 'No (N)'	System	23 Sep 2020 04:59:29
	System	23 Sep 2020 04:59:29

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

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 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T23:59:24', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '61db9c97-b127-476f-ac03-3b66974be855' User entered 'None (1)'	System	23 Sep 2020 04:59:29
	System	23 Sep 2020 04:59:29

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T23:59:26', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '61db9c97-b127-476f-ac03-3b66974be855' User entered '22 Sep 2020 23:59'	System	23 Sep 2020 04:59:29
	System	23 Sep 2020 04:59:29

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '22 Sep 2020 15:58'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	22 Sep 2020 17:48:44
User entered 'Day 2'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:25

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 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-23T16:47:48', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '06b96ddb-549c-49d5-832f-7281e60f8dc7' User entered 'None (1)'	System	23 Sep 2020 21:48:06
	System	23 Sep 2020 21:48:06

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-23T16:47:55', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '06b96ddb-549c-49d5-832f-7281e60f8dc7' User entered 'No (N)'	System	23 Sep 2020 21:48:06
	System	23 Sep 2020 21:48:06

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-23T16:47:57', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '06b96ddb-549c-49d5-832f-7281e60f8dc7' User entered 'No (N)'	System	23 Sep 2020 21:48:06
	System	23 Sep 2020 21:48:06

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:25

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 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-23T16:47:58', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '06b96ddb-549c-49d5-832f-7281e60f8dc7'	System	23 Sep 2020 21:48:06
User entered 'None (1)'	System	23 Sep 2020 21:48:06

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-23T16:48:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '06b96ddb-549c-49d5-832f-7281e60f8dc7' User entered '23 Sep 2020 16:48'	System	23 Sep 2020 21:48:06
	System	23 Sep 2020 21:48:06

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	22 Sep 2020 17:48:44
User entered 'Day 3'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:25

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 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-24T15:15:05', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'e1a2ef11-79d8-4d3e-8601-bf9c8288fc0b' User entered 'None (1)'	System	24 Sep 2020 20:15:18
	System	24 Sep 2020 20:15:18

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-24T15:15:08', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'e1a2ef11-79d8-4d3e-8601-bf9c8288fc0b' User entered 'No (N)'	System	24 Sep 2020 20:15:18
	System	24 Sep 2020 20:15:18

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-24T15:15:12', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'e1a2ef11-79d8-4d3e-8601-bf9c8288fc0b' User entered 'No (N)'	System	24 Sep 2020 20:15:18
	System	24 Sep 2020 20:15:18

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:25

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 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-24T15:15:14', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'e1a2ef11-79d8-4d3e-8601-bf9c8288fc0b' User entered 'None (1)'	System	24 Sep 2020 20:15:18
	System	24 Sep 2020 20:15:18

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-24T15:15:16', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'e1a2ef11-79d8-4d3e-8601-bf9c8288fc0b' User entered '24 Sep 2020 15:15'	System	24 Sep 2020 20:15:18
	System	24 Sep 2020 20:15:18

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	22 Sep 2020 17:48:44
User entered 'Day 4'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:25

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 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-25T23:59:23', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'bd94db18-8442-4a60-a101-942f50b35f71' User entered 'None (1)'	System	26 Sep 2020 04:59:32
	System	26 Sep 2020 04:59:32

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-25T23:59:25', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'bd94db18-8442-4a60-a101-942f50b35f71' User entered 'No (N)'	System	26 Sep 2020 04:59:32
	System	26 Sep 2020 04:59:32

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-25T23:59:26', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'bd94db18-8442-4a60-a101-942f50b35f71' User entered 'No (N)'	System	26 Sep 2020 04:59:32
	System	26 Sep 2020 04:59:32

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:25

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 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-25T23:59:27', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'bd94db18-8442-4a60-a101-942f50b35f71' User entered 'None (1)'	System	26 Sep 2020 04:59:32
	System	26 Sep 2020 04:59:32

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-25T23:59:29', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'bd94db18-8442-4a60-a101-942f50b35f71' User entered '25 Sep 2020 23:59'	System	26 Sep 2020 04:59:32
	System	26 Sep 2020 04:59:32

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	22 Sep 2020 17:48:44
User entered 'Day 5'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:25

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 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-26T13:58:02', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'f25c79c7-9e12-4ca8-ae5c-bbfea9b506d2' User entered 'None (1)'	System	26 Sep 2020 18:58:09
	System	26 Sep 2020 18:58:09

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-26T13:58:04', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'f25c79c7-9e12-4ca8-ae5c-bbfea9b506d2' User entered 'No (N)'	System	26 Sep 2020 18:58:09
	System	26 Sep 2020 18:58:09

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-26T13:58:05', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'f25c79c7-9e12-4ca8-ae5c-bbfea9b506d2'	System	26 Sep 2020 18:58:09
User entered 'No (N)'	System	26 Sep 2020 18:58:09

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:25

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 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-26T13:58:06', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'f25c79c7-9e12-4ca8-ae5c-bbfea9b506d2'	System	26 Sep 2020 18:58:09
User entered 'None (1)'	System	26 Sep 2020 18:58:09

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-26T13:58:08', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'f25c79c7-9e12-4ca8-ae5c-bbfea9b506d2' User entered '26 Sep 2020 13:58'	System	26 Sep 2020 18:58:09
	System	26 Sep 2020 18:58:09

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	22 Sep 2020 17:48:44
User entered 'Day 6'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:25

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 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-27T20:23:15', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '9a1caa82-49cf-4fa3-9ed8-1eb92ac290e7' User entered 'None (1)'	System	28 Sep 2020 01:23:22
	System	28 Sep 2020 01:23:22

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-27T20:23:16', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '9a1caa82-49cf-4fa3-9ed8-1eb92ac290e7' User entered 'No (N)'	System	28 Sep 2020 01:23:22
	System	28 Sep 2020 01:23:22

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-27T20:23:17', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '9a1caa82-49cf-4fa3-9ed8-1eb92ac290e7' User entered 'No (N)'	System	28 Sep 2020 01:23:22
	System	28 Sep 2020 01:23:22

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:25

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 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-27T20:23:18', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '9a1caa82-49cf-4fa3-9ed8-1eb92ac290e7' User entered 'None (1)'	System	28 Sep 2020 01:23:22
	System	28 Sep 2020 01:23:22

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-27T20:23:20', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '9a1caa82-49cf-4fa3-9ed8-1eb92ac290e7' User entered '27 Sep 2020 20:23'	System	28 Sep 2020 01:23:22
	System	28 Sep 2020 01:23:22

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	22 Sep 2020 17:48:44
User entered 'Day 7'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:25

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 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-29T00:47:31', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '4a41a36e-37b2-45a4-bfd3-a7ea4615699e' User entered 'None (1)'	System	29 Sep 2020 05:47:40
	System	29 Sep 2020 05:47:40

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-29T00:47:33', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '4a41a36e-37b2-45a4-bfd3-a7ea4615699e' User entered 'No (N)'	System	29 Sep 2020 05:47:40
	System	29 Sep 2020 05:47:40

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-29T00:47:34', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '4a41a36e-37b2-45a4-bfd3-a7ea4615699e' User entered 'No (N)'	System	29 Sep 2020 05:47:40
	System	29 Sep 2020 05:47:40

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:25

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 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-29T00:47:35', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '4a41a36e-37b2-45a4-bfd3-a7ea4615699e' User entered 'None (1)'	System	29 Sep 2020 05:47:40
	System	29 Sep 2020 05:47:40

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-29T00:47:37', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '4a41a36e-37b2-45a4-bfd3-a7ea4615699e' User entered '29 Sep 2020 00:47'	System	29 Sep 2020 05:47:40
	System	29 Sep 2020 05:47:40

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	22 Sep 2020 17:48:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T12:50:48', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '93d88e71-7120-4132-be08-3515f2a06dc5' User entered 'None (0)'	System	22 Sep 2020 17:51:07
	System	22 Sep 2020 17:51:07

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T12:50:50', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '93d88e71-7120-4132-be08-3515f2a06dc5' User entered 'None (0)'	System	22 Sep 2020 17:51:07
	System	22 Sep 2020 17:51:07

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T12:50:52', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '93d88e71-7120-4132-be08-3515f2a06dc5' User entered 'None (0)'	System	22 Sep 2020 17:51:07
	System	22 Sep 2020 17:51:07

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T12:50:54', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '93d88e71-7120-4132-be08-3515f2a06dc5' User entered 'None (0)'	System	22 Sep 2020 17:51:07
	System	22 Sep 2020 17:51:07

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T12:50:56', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '93d88e71-7120-4132-be08-3515f2a06dc5' User entered 'None (0)'	System	22 Sep 2020 17:51:07
	System	22 Sep 2020 17:51:07

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T12:50:57', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '93d88e71-7120-4132-be08-3515f2a06dc5' User entered 'None (0)'	System	22 Sep 2020 17:51:07
	System	22 Sep 2020 17:51:07

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

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 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T12:51:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '93d88e71-7120-4132-be08-3515f2a06dc5' User entered 'No (N)'	System	22 Sep 2020 17:51:07
	System	22 Sep 2020 17:51:07

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T12:51:02', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '93d88e71-7120-4132-be08-3515f2a06dc5' User entered '22 Sep 2020 12:51'	System	22 Sep 2020 17:51:07
	System	22 Sep 2020 17:51:07

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '22 Sep 2020 12:33'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '22 Sep 2020 15:03'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	22 Sep 2020 17:48:44
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T23:59:29', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '598a293b-fad8-4592-9ce8-673bb3c60431' User entered 'None (0)'	System	23 Sep 2020 04:59:43
	System	23 Sep 2020 04:59:43

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T23:59:30', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '598a293b-fad8-4592-9ce8-673bb3c60431' User entered 'None (0)'	System	23 Sep 2020 04:59:43
	System	23 Sep 2020 04:59:43

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T23:59:32', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '598a293b-fad8-4592-9ce8-673bb3c60431' User entered 'None (0)'	System	23 Sep 2020 04:59:43
	System	23 Sep 2020 04:59:43

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T23:59:33', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '598a293b-fad8-4592-9ce8-673bb3c60431' User entered 'None (0)'	System	23 Sep 2020 04:59:43
	System	23 Sep 2020 04:59:43

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T23:59:34', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '598a293b-fad8-4592-9ce8-673bb3c60431' User entered 'None (0)'	System	23 Sep 2020 04:59:43
	System	23 Sep 2020 04:59:43

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T23:59:36', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '598a293b-fad8-4592-9ce8-673bb3c60431' User entered 'None (0)'	System	23 Sep 2020 04:59:43
	System	23 Sep 2020 04:59:43

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

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 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T23:59:38', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '598a293b-fad8-4592-9ce8-673bb3c60431' User entered 'No (N)'	System	23 Sep 2020 04:59:43
	System	23 Sep 2020 04:59:43

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-22T23:59:40', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '598a293b-fad8-4592-9ce8-673bb3c60431' User entered '22 Sep 2020 23:59'	System	23 Sep 2020 04:59:43
	System	23 Sep 2020 04:59:43

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '22 Sep 2020 15:58'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	22 Sep 2020 17:48:44
User entered 'Day 2'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-23T16:48:02', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'd9a3b848-64de-401e-8f93-47abcb8a7cd5' User entered 'None (0)'	System	23 Sep 2020 21:48:23
	System	23 Sep 2020 21:48:23

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-23T16:48:04', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'd9a3b848-64de-401e-8f93-47abcb8a7cd5' User entered 'None (0)'	System	23 Sep 2020 21:48:23
	System	23 Sep 2020 21:48:23

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-23T16:48:05', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'd9a3b848-64de-401e-8f93-47abcb8a7cd5' User entered 'None (0)'	System	23 Sep 2020 21:48:23
	System	23 Sep 2020 21:48:23

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-23T16:48:06', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'd9a3b848-64de-401e-8f93-47abcb8a7cd5' User entered 'None (0)'	System	23 Sep 2020 21:48:23
	System	23 Sep 2020 21:48:23

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-23T16:48:07', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'd9a3b848-64de-401e-8f93-47abcb8a7cd5' User entered 'None (0)'	System	23 Sep 2020 21:48:23
	System	23 Sep 2020 21:48:23

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-23T16:48:09', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'd9a3b848-64de-401e-8f93-47abcb8a7cd5' User entered 'None (0)'	System	23 Sep 2020 21:48:23
	System	23 Sep 2020 21:48:23

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:25

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 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-23T16:48:17', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'd9a3b848-64de-401e-8f93-47abcb8a7cd5' User entered 'No (N)'	System	23 Sep 2020 21:48:23
	System	23 Sep 2020 21:48:23

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-23T16:48:19', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'd9a3b848-64de-401e-8f93-47abcb8a7cd5' User entered '23 Sep 2020 16:48'	System	23 Sep 2020 21:48:23
	System	23 Sep 2020 21:48:23

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	22 Sep 2020 17:48:44
User entered 'Day 3'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-24T15:15:19', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '8e3ad1d9-e52d-462b-90f0-69a8edb6b086' User entered 'None (0)'	System	24 Sep 2020 20:15:38
	System	24 Sep 2020 20:15:38

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-24T15:15:22', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '8e3ad1d9-e52d-462b-90f0-69a8edb6b086'	System	24 Sep 2020 20:15:38
User entered 'No interference with activity (1)'	System	24 Sep 2020 20:15:38

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-24T15:15:24', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '8e3ad1d9-e52d-462b-90f0-69a8edb6b086' User entered 'None (0)'	System	24 Sep 2020 20:15:38
	System	24 Sep 2020 20:15:38

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-24T15:15:26', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '8e3ad1d9-e52d-462b-90f0-69a8edb6b086' User entered 'None (0)'	System	24 Sep 2020 20:15:38
	System	24 Sep 2020 20:15:38

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-24T15:15:28', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '8e3ad1d9-e52d-462b-90f0-69a8edb6b086' User entered 'None (0)'	System	24 Sep 2020 20:15:38
	System	24 Sep 2020 20:15:38

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-24T15:15:30', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '8e3ad1d9-e52d-462b-90f0-69a8edb6b086' User entered 'None (0)'	System	24 Sep 2020 20:15:38
	System	24 Sep 2020 20:15:38

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:25

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 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-24T15:15:32', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '8e3ad1d9-e52d-462b-90f0-69a8edb6b086' User entered 'No (N)'	System	24 Sep 2020 20:15:38
	System	24 Sep 2020 20:15:38

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-24T15:15:35', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '8e3ad1d9-e52d-462b-90f0-69a8edb6b086' User entered '24 Sep 2020 15:15'	System	24 Sep 2020 20:15:38
	System	24 Sep 2020 20:15:38

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	22 Sep 2020 17:48:44
User entered 'Day 4'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-25T23:59:31', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'e8db9b9b-b46c-4eb6-8675-b52965d69c42'	System	26 Sep 2020 04:59:42
User entered 'None (0)'	System	26 Sep 2020 04:59:42

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-25T23:59:32', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'e8db9b9b-b46c-4eb6-8675-b52965d69c42' User entered 'None (0)'	System	26 Sep 2020 04:59:42
	System	26 Sep 2020 04:59:42

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-25T23:59:33', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'e8db9b9b-b46c-4eb6-8675-b52965d69c42' User entered 'None (0)'	System	26 Sep 2020 04:59:42
	System	26 Sep 2020 04:59:42

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-25T23:59:34', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'e8db9b9b-b46c-4eb6-8675-b52965d69c42' User entered 'None (0)'	System	26 Sep 2020 04:59:42
	System	26 Sep 2020 04:59:42

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-25T23:59:35', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'e8db9b9b-b46c-4eb6-8675-b52965d69c42'	System	26 Sep 2020 04:59:42
User entered 'None (0)'	System	26 Sep 2020 04:59:42

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-25T23:59:37', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'e8db9b9b-b46c-4eb6-8675-b52965d69c42' User entered 'None (0)'	System	26 Sep 2020 04:59:42
	System	26 Sep 2020 04:59:42

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:25

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 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-25T23:59:38', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'e8db9b9b-b46c-4eb6-8675-b52965d69c42'	System	26 Sep 2020 04:59:42
User entered 'No (N)'	System	26 Sep 2020 04:59:42

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-25T23:59:40', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'e8db9b9b-b46c-4eb6-8675-b52965d69c42'	System	26 Sep 2020 04:59:42
User entered '25 Sep 2020 23:59'	System	26 Sep 2020 04:59:42

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	22 Sep 2020 17:48:44
User entered 'Day 5'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-26T13:58:10', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '71476602-eb01-49cf-abc-b-68312b616a10' User entered 'None (0)'	System	26 Sep 2020 18:58:23
	System	26 Sep 2020 18:58:23

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-26T13:58:11', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '71476602-eb01-49cf-abcb-68312b616a10' User entered 'None (0)'	System	26 Sep 2020 18:58:23
	System	26 Sep 2020 18:58:23

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-26T13:58:12', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '71476602-eb01-49cf-abc-b-68312b616a10' User entered 'None (0)'	System	26 Sep 2020 18:58:23
	System	26 Sep 2020 18:58:23

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-26T13:58:13', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '71476602-eb01-49cf-abcb-68312b616a10' User entered 'None (0)'	System	26 Sep 2020 18:58:23
	System	26 Sep 2020 18:58:23

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-26T13:58:15', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '71476602-eb01-49cf-abc-b-68312b616a10' User entered 'None (0)'	System	26 Sep 2020 18:58:23
	System	26 Sep 2020 18:58:23

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-26T13:58:16', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '71476602-eb01-49cf-abc-b-68312b616a10' User entered 'None (0)'	System	26 Sep 2020 18:58:23
	System	26 Sep 2020 18:58:23

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:25

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 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-26T13:58:17', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '71476602-eb01-49cf-abc-b68312b616a10' User entered 'No (N)'	System	26 Sep 2020 18:58:23
	System	26 Sep 2020 18:58:23

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-26T13:58:20', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '71476602-eb01-49cf-abc-b68312b616a10' User entered '26 Sep 2020 13:58'	System	26 Sep 2020 18:58:23
	System	26 Sep 2020 18:58:23

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	22 Sep 2020 17:48:44
User entered 'Day 6'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-27T20:23:22', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'a53ab133-e46a-4d3e-af02-f4d7506e38fc' User entered 'None (0)'	System	28 Sep 2020 01:23:36
	System	28 Sep 2020 01:23:36

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-27T20:23:23', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'a53ab133-e46a-4d3e-af02-f4d7506e38fc' User entered 'None (0)'	System	28 Sep 2020 01:23:36
	System	28 Sep 2020 01:23:36

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-27T20:23:24', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'a53ab133-e46a-4d3e-af02-f4d7506e38fc' User entered 'None (0)'	System	28 Sep 2020 01:23:36
	System	28 Sep 2020 01:23:36

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-27T20:23:26', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'a53ab133-e46a-4d3e-af02-f4d7506e38fc' User entered 'None (0)'	System	28 Sep 2020 01:23:36
	System	28 Sep 2020 01:23:36

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-27T20:23:27', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'a53ab133-e46a-4d3e-af02-f4d7506e38fc' User entered 'None (0)'	System	28 Sep 2020 01:23:36
	System	28 Sep 2020 01:23:36

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-27T20:23:28', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'a53ab133-e46a-4d3e-af02-f4d7506e38fc' User entered 'None (0)'	System	28 Sep 2020 01:23:36
	System	28 Sep 2020 01:23:36

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:25

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 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-27T20:23:31', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'a53ab133-e46a-4d3e-af02-f4d7506e38fc' User entered 'No (N)'	System	28 Sep 2020 01:23:36
	System	28 Sep 2020 01:23:36

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-27T20:23:32', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'a53ab133-e46a-4d3e-af02-f4d7506e38fc' User entered '27 Sep 2020 20:23'	System	28 Sep 2020 01:23:36
	System	28 Sep 2020 01:23:36

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	22 Sep 2020 17:48:44
User entered 'Day 7'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:25

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-29T00:47:41', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'bd92d5b9-5cd8-408e-a1d2-f93b20b96b48' User entered 'None (0)'	System	29 Sep 2020 05:47:53
	System	29 Sep 2020 05:47:53

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:25

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-29T00:47:42', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'bd92d5b9-5cd8-408e-a1d2-f93b20b96b48' User entered 'None (0)'	System	29 Sep 2020 05:47:53
	System	29 Sep 2020 05:47:53

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:25

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-29T00:47:43', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'bd92d5b9-5cd8-408e-a1d2-f93b20b96b48' User entered 'None (0)'	System	29 Sep 2020 05:47:53
	System	29 Sep 2020 05:47:53

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:25

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-29T00:47:45', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'bd92d5b9-5cd8-408e-a1d2-f93b20b96b48' User entered 'None (0)'	System	29 Sep 2020 05:47:53
	System	29 Sep 2020 05:47:53

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:25

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-29T00:47:46', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'bd92d5b9-5cd8-408e-a1d2-f93b20b96b48' User entered 'None (0)'	System	29 Sep 2020 05:47:53
	System	29 Sep 2020 05:47:53

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:25

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-29T00:47:48', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'bd92d5b9-5cd8-408e-a1d2-f93b20b96b48' User entered 'None (0)'	System	29 Sep 2020 05:47:53
	System	29 Sep 2020 05:47:53

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:25

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 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-29T00:47:49', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'bd92d5b9-5cd8-408e-a1d2-f93b20b96b48' User entered 'No (N)'	System	29 Sep 2020 05:47:53
	System	29 Sep 2020 05:47:53

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:25

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-09-29T00:47:51', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'bd92d5b9-5cd8-408e-a1d2-f93b20b96b48' User entered '29 Sep 2020 00:47'	System	29 Sep 2020 05:47:53
	System	29 Sep 2020 05:47:53

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 17:48:44

US3572076

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:17:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 17:48:44

US3572076

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	02 Oct 2020 00:11:03

US3572076

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '1 Oct 2020'	(b) (4) Jackie Ziegler (b) (4)	02 Oct 2020 00:11:03

US3572076

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:21
User signature succeeded.	Milton Haber (b) (4) (b) (4)	20 Mar 2021 23:47:54
User entered 'Contact Made (CONTACT MADE)'	Jackie Ziegler (b) (4) (b) (4)	02 Oct 2020 00:11:03

US3572076

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	02 Oct 2020 00:11:03
	(b) (4)	

US3572076

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:21
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	02 Oct 2020 00:11:08

US3572076

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:21
User entered 'I'	System	02 Oct 2020 00:11:08

US3572076

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	07 Oct 2020 15:06:06

US3572076

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '7 Oct 2020'	(b) (4) Jackie Ziegler (b) (4)	07 Oct 2020 15:06:06

US3572076

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4) (b) (4)	20 Mar 2021 23:47:54
User entered 'Contact Made (CONTACT MADE)'	Jackie Ziegler (b) (4) (b) (4)	07 Oct 2020 15:06:06

US3572076

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	07 Oct 2020 15:06:06
	(b) (4)	

US3572076

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	07 Oct 2020 15:06:11

US3572076

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered 'l'	System	07 Oct 2020 15:06:11

US3572076

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	13 Oct 2020 18:36:25

US3572076

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '13 Oct 2020'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	13 Oct 2020 18:36:25

US3572076

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4) (b) (4)	20 Mar 2021 23:47:54
User entered 'Contact Made (CONTACT MADE)'	Jackie Ziegler (b) (4) (b) (4)	13 Oct 2020 18:36:25

US3572076

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4) (b) (4)	20 Mar 2021 23:47:54
User entered empty.	Jackie Ziegler (b) (4) (b) (4)	13 Oct 2020 18:36:25

US3572076

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	13 Oct 2020 18:36:30

US3572076

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered 'I'	System	13 Oct 2020 18:36:30

US3572076

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re- Query: Thank you for your response, however please note that, as Unscheduled folder does not have provision to record the SARS-COV-2 sample in EDC, we need to update the SARS-COV-2 sample data only in Illness visit folder, under Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection form only, hence we need to transfer all this data in those forms and inactivate the unscheduled visit forms accordingly. As per CCG V 2.0, pg 14 & 16, please initiate the illness visit using Add Event option and record the SARS-CoV-2 sample dated 01 SEP 2020 under Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection form as appropriate. Please inactivate unscheduled visit forms as it leads to unnecessary confusion of a new Immuno sample in EDC. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:07:38

US3572076

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re- Query: Thank you for your response, however please note that, as Unscheduled folder does not have provision to record the SARS-COV-2 sample in EDC, we need to update the SARS-COV-2 sample data only in Illness visit folder, under Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection form only, hence we need to transfer all this data in those forms and inactivate the unscheduled visit forms accordingly. As per CCG V 2.0, pg 14 & 16, please initiate the illness visit using Add Event option and record the SARS-CoV-2 sample dated 01 SEP 2020 under Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection form as appropriate. Please inactivate unscheduled visit forms as it leads to unnecessary confusion of a new Immuno sample in EDC. Thank you.' answered with 'All data for Illness visit and samples collected on 01 SEP 2020 have been updated in EDC ' (Site from DM).	Alisha Lutat (b) (4)	16 Feb 2021 22:11:09
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re- Query: Thank you for your response, however please note that, as Unscheduled folder does not have provision to record the SARS-COV-2 sample in EDC, we need to update the SARS-COV-2 sample data only in Illness visit folder, under Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection form only, hence we need to transfer all this data in those forms and inactivate the unscheduled visit forms accordingly. As per CCG V 2.0, pg 14 & 16, please initiate the illness visit using Add Event option and record the SARS-CoV-2 sample dated 01 SEP 2020 under Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection form as appropriate. Please inactivate unscheduled visit forms as it leads to unnecessary confusion of a new Immuno sample in EDC. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 07:28:19

US3572076

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
User closed query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 01 SEP 2020 is reported under UNSCHEDULED 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). Query '	(b) (4), (b) (6)	11 Jan 2021 07:28:19
Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 01 SEP 2020 is reported under UNSCHEDULED 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.'	(b) (4), (b) (6)	07 Jan 2021 00:58:02
answered with 'Unscheduled Visit on 01SEP2020 has been added to EDC' (Site from DM). User opened query '	(b) (4), (b) (6)	10 Nov 2020 07:51:55
Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 01 SEP 2020 is reported under UNSCHEDULED 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)	
User entered 'Yes (Y)'	Maria Candelario (b) (4) (b) (4)	26 Oct 2020 11:02:41

US3572076

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '21 Oct 2020'	(b) (4) Maria Candelario (b) (4)	26 Oct 2020 11:02:41

US3572076

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Clinic (Clinic)'	(b) (4) Maria Candelario (b) (4) (b) (4)	26 Oct 2020 11:02:41

US3572076

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered 'VISIT3'	System	26 Oct 2020 11:02:41

US3572076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Maria Candelario (b) (4)	26 Oct 2020 11:04:28

US3572076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '21 Oct 2020'	(b) (4) Maria Candelario (b) (4)	26 Oct 2020 11:04:28

US3572076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '09:30'	(b) (4) Maria Candelario (b) (4) (b) (4)	26 Oct 2020 11:04:28

US3572076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered '21 Oct 2020 09:30'	System	26 Oct 2020 11:04:28

US3572076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '97.7' F	(b) (4) Maria Candelario (b) (4)	26 Oct 2020 11:04:28

US3572076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Other (Other)'	(b) (4) Maria Candelario (b) (4)	26 Oct 2020 11:04:28

US3572076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'temporal'	(b) (4) Maria Candelario (b) (4)	26 Oct 2020 11:04:28

US3572076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '87'	(b) (4) Maria Candelario (b) (4) (b) (4)	26 Oct 2020 11:04:28

US3572076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered 'bpm'	System	26 Oct 2020 11:04:28

US3572076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '18'	(b) (4) Maria Candelario (b) (4)	26 Oct 2020 11:04:28

US3572076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered 'breaths/min'	System	26 Oct 2020 11:04:28

US3572076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '121'	(b) (4) Maria Candelario (b) (4)	26 Oct 2020 11:04:28

US3572076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered 'mmHg'	System	26 Oct 2020 11:04:28

US3572076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '72'	(b) (4) Maria Candelario (b) (4)	26 Oct 2020 11:04:28

US3572076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered 'mmHg'	System	26 Oct 2020 11:04:28

US3572076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38

US3572076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38

US3572076

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Maria Candelario (b) (4)	26 Oct 2020 11:04:38

US3572076

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '21 Oct 2020'	(b) (4) Maria Candelario (b) (4)	26 Oct 2020 11:04:38

US3572076

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Maria Candelario (b) (4)	26 Oct 2020 11:05:06

US3572076

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '21 Oct 2020'	(b) (4) Maria Candelario (b) (4)	26 Oct 2020 11:05:06

US3572076

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered '09:41'	(b) (4) Maria Candelario (b) (4) (b) (4)	26 Oct 2020 11:05:06

US3572076

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered '21 Oct 2020 09:41'	System	26 Oct 2020 11:05:06

US3572076

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User signature succeeded.	Milton Haber (b) (4)	20 Mar 2021 23:47:54
User entered 'Yes (Y)'	(b) (4) Maria Candelario (b) (4)	26 Oct 2020 11:05:11

US3572076

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:58:38
User entered 'I'	System	26 Oct 2020 11:05:11

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	24 Aug 2020 17:45:09
User entered 'Day 64'	System	24 Aug 2020 17:45:09

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-10-24T00:03:28', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '2d9f1836-067d-4115-9de2-03d61bacd751' User entered 'No (N)'	System	24 Oct 2020 05:03:38
	System	24 Oct 2020 05:03:38

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-10-24T00:03:31', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '2d9f1836-067d-4115-9de2-03d61bacd751'	System	24 Oct 2020 05:03:38
User entered 'No (N)'	System	24 Oct 2020 05:03:38

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (717ACA73-5BB8-4542-AAE4-742CE31EFBBE)', Time: '2020-10-24T00:03:34', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '2d9f1836-067d-4115-9de2-03d61bacd751' User entered '24 Oct 2020 00:03:34'	System	24 Oct 2020 05:03:38
	System	24 Oct 2020 05:03:38

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	24 Aug 2020 17:45:09
User entered '24 Oct 2020 00:01'	System	24 Aug 2020 17:45:09

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:48:54
Data entry locked.	System	24 Aug 2020 17:45:09
User entered '28 Oct 2020 23:59'	System	24 Aug 2020 17:45:09

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21
Data entry locked.	System	24 Aug 2020 17:45:09
User entered 'Day 71'	System	24 Aug 2020 17:45:09

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[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 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Have you been exposed to someone with 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 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Please 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 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[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 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Please 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 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[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 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Please 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 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21
Data entry locked.	System	24 Aug 2020 17:45:09
User entered '31 Oct 2020 00:01'	System	24 Aug 2020 17:45:09

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21
Data entry locked.	System	24 Aug 2020 17:45:09
User entered '04 Nov 2020 23:59'	System	24 Aug 2020 17:45:09

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21
Data entry locked.	System	24 Aug 2020 17:45:09
User entered 'Day 78'	System	24 Aug 2020 17:45:09

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[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 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Have you been exposed to someone with 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 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Please 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 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[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 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Please 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 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[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 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Please 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 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21
Data entry locked.	System	24 Aug 2020 17:45:09
User entered '07 Nov 2020 00:01'	System	24 Aug 2020 17:45:09

US3572076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:47:21
Data entry locked.	System	24 Aug 2020 17:45:09
User entered '11 Nov 2020 23:59'	System	24 Aug 2020 17:45:09

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2020-12-17T15:18:57', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '82774c03-affc-4d67-8f9b-dae7c5f12987' User entered 'No (N)'	System	17 Dec 2020 21:19:22
	System	17 Dec 2020 21:19:22

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2020-12-17T15:19:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '82774c03-affc-4d67-8f9b-dae7c5f12987' User entered 'Yes (Y)'	System	17 Dec 2020 21:19:22
	System	17 Dec 2020 21:19:22

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2020-12-17T15:19:07', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '82774c03-affc-4d67-8f9b-dae7c5f12987'	System	17 Dec 2020 21:19:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Dec 2020 21:19:22

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2020-12-17T15:19:10', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '82774c03-affc-4d67-8f9b-dae7c5f12987' User entered '17 Dec 2020 15:19:10'	System	17 Dec 2020 21:19:22
	System	17 Dec 2020 21:19:22

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 10:25:33
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'per source no AEs, new meds, or procedures' (Site from DM).	Caitlin roll (b) (4)	08 Apr 2021 17:55:34
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Mar 2021 13:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2020-12-23T03:15:17', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'f786fbf9-9116-4842-a408-96138146b656'	System	23 Dec 2020 09:16:09
User entered 'Yes (Y)'	System	23 Dec 2020 09:16:09

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2020-12-23T03:15:33', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'f786fbf9-9116-4842-a408-96138146b656' User entered 'Yes (Y)'	System	23 Dec 2020 09:16:09
	System	23 Dec 2020 09:16:09

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2020-12-23T03:15:40', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'f786fbf9-9116-4842-a408-96138146b656'	System	23 Dec 2020 09:16:09
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Dec 2020 09:16:09

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2020-12-23T03:15:44', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'f786fbf9-9116-4842-a408-96138146b656' User entered 'No (N)'	System	23 Dec 2020 09:16:09
	System	23 Dec 2020 09:16:09

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2020-12-23T03:15:50', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'f786fbf9-9116-4842-a408-96138146b656' User entered 'Yes (Y)'	System	23 Dec 2020 09:16:09
	System	23 Dec 2020 09:16:09

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2020-12-23T03:15:55', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'f786fbf9-9116-4842-a408-96138146b656'	System	23 Dec 2020 09:16:09
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Dec 2020 09:16:09

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2020-12-23T03:15:59', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'f786fbf9-9116-4842-a408-96138146b656' User entered '23 Dec 2020 03:15:59'	System	23 Dec 2020 09:16:09
	System	23 Dec 2020 09:16:09

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2020-12-30T00:04:48', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '76fb2de8-6f77-4644-b812-585df2c07011' User entered 'No (N)'	System	30 Dec 2020 06:05:10
	System	30 Dec 2020 06:05:10

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2020-12-30T00:04:53', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '76fb2de8-6f77-4644-b812-585df2c07011' User entered 'Yes (Y)'	System	30 Dec 2020 06:05:10
	System	30 Dec 2020 06:05:10

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2020-12-30T00:04:55', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '76fb2de8-6f77-4644-b812-585df2c07011'	System	30 Dec 2020 06:05:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Dec 2020 06:05:10

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2020-12-30T00:04:57', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '76fb2de8-6f77-4644-b812-585df2c07011' User entered '30 Dec 2020 00:04:57'	System	30 Dec 2020 06:05:10
	System	30 Dec 2020 06:05:10

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-01-06T00:01:25', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'd653e5b9-5234-471d-8320-fee93acf3741' User entered 'No (N)'	System	06 Jan 2021 06:01:41

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-01-06T00:01:28', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'd653e5b9-5234-471d-8320-fee93acf3741' User entered 'No (N)'	System	06 Jan 2021 06:01:41

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-01-06T00:01:32', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'd653e5b9-5234-471d-8320-fee93acf3741' User entered '06 Jan 2021 00:01:32'	System	06 Jan 2021 06:01:41
	System	06 Jan 2021 06:01:41

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-01-13T13:34:28', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'd49828f9-0a70-4b72-bf41-e4ef6de4954e' User entered 'No (N)'	System	13 Jan 2021 19:34:34

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-01-13T13:34:30', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'd49828f9-0a70-4b72-bf41-e4ef6de4954e' User entered 'No (N)'	System	13 Jan 2021 19:34:34

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-01-13T13:34:32', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'd49828f9-0a70-4b72-bf41-e4ef6de4954e' User entered '13 Jan 2021 13:34:32'	System	13 Jan 2021 19:34:34

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-01-20T00:01:17', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '9e3ffb6e-bcf4-4c43-8ac2-4b0312d51350'	System	20 Jan 2021 06:01:31
User entered 'No (N)'	System	20 Jan 2021 06:01:31

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-01-20T00:01:22', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '9e3ffb6e-bcf4-4c43-8ac2-4b0312d51350' User entered 'No (N)'	System	20 Jan 2021 06:01:31

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-01-20T00:01:24', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '9e3ffb6e-bcf4-4c43-8ac2-4b0312d51350' User entered '20 Jan 2021 00:01:24'	System	20 Jan 2021 06:01:31
	System	20 Jan 2021 06:01:31

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-01-29T12:01:04', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'a9590988-ac73-4559-9bfb-b8baef977c3a' User entered 'No (N)'	System	29 Jan 2021 18:02:11

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-01-29T12:01:07', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'a9590988-ac73-4559-9bfb-b8baef977c3a' User entered 'No (N)'	System	29 Jan 2021 18:02:11

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-01-29T12:01:09', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'a9590988-ac73-4559-9bfb-b8baef977c3a' User entered '29 Jan 2021 12:01:09'	System	29 Jan 2021 18:02:11
	System	29 Jan 2021 18:02:11

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-02-03T00:18:15', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'cbd3e6a9-8556-4573-863c-26f1e73f1b8f' User entered 'No (N)'	System	03 Feb 2021 06:18:22
	System	03 Feb 2021 06:18:22

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-02-03T00:18:16', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'cbd3e6a9-8556-4573-863c-26f1e73f1b8f' User entered 'No (N)'	System	03 Feb 2021 06:18:22

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-02-03T00:18:19', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'cbd3e6a9-8556-4573-863c-26f1e73f1b8f' User entered '03 Feb 2021 00:18:19'	System	03 Feb 2021 06:18:22
	System	03 Feb 2021 06:18:22

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-02-10T12:55:16', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '30a9ce63-5640-452f-8cbe-127f5342d088' User entered 'No (N)'	System	10 Feb 2021 18:55:37

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-02-10T12:55:19', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '30a9ce63-5640-452f-8cbe-127f5342d088' User entered 'No (N)'	System	10 Feb 2021 18:55:37

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-02-10T12:55:33', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '30a9ce63-5640-452f-8cbe-127f5342d088' User entered '10 Feb 2021 12:55:33'	System	10 Feb 2021 18:55:37
	System	10 Feb 2021 18:55:37

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-02-17T00:55:01', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'd7f2b0bc-a583-4b3e-aab1-f0a5f3542ae9' User entered 'No (N)'	System	17 Feb 2021 06:55:12

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-02-17T00:55:03', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'd7f2b0bc-a583-4b3e-aab1-f0a5f3542ae9' User entered 'No (N)'	System	17 Feb 2021 06:55:12

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-02-17T00:55:10', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'd7f2b0bc-a583-4b3e-aab1-f0a5f3542ae9' User entered '17 Feb 2021 00:55:10'	System	17 Feb 2021 06:55:12
	System	17 Feb 2021 06:55:12

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-02-24T00:04:29', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '3faa92fd-1687-44aa-885b-72f30d76a765' User entered 'No (N)'	System	24 Feb 2021 06:04:37

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-02-24T00:04:31', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '3faa92fd-1687-44aa-885b-72f30d76a765' User entered 'No (N)'	System	24 Feb 2021 06:04:37

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-02-24T00:04:33', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '3faa92fd-1687-44aa-885b-72f30d76a765' User entered '24 Feb 2021 00:04:33'	System	24 Feb 2021 06:04:37
	System	24 Feb 2021 06:04:37

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-03-03T00:01:18-06:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '39c99ca2-95b2-4af6-a647-412efb4f85f3'	System	03 Mar 2021 06:01:27
User entered 'No (N)'	System	03 Mar 2021 06:01:27

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-03-03T00:01:21-06:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '39c99ca2-95b2-4af6-a647-412efb4f85f3'	System	03 Mar 2021 06:01:27
User entered 'No (N)'	System	03 Mar 2021 06:01:27

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-03-03T00:01:24-06:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '39c99ca2-95b2-4af6-a647-412efb4f85f3'	System	03 Mar 2021 06:01:27
User entered '03 Mar 2021 06:01:24'	System	03 Mar 2021 06:01:27

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-03-10T00:03:36-06:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '5bcd6cb7-925d-4a3c-b2fc-6744e75edbe4'	System	17 Mar 2021 05:02:40
User entered 'No (N)'	System	17 Mar 2021 05:02:40

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-03-10T00:03:39-06:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '5bcd6cb7-925d-4a3c-b2fc-6744e75edbe4'	System	17 Mar 2021 05:02:40
User entered 'No (N)'	System	17 Mar 2021 05:02:40

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-03-10T00:03:41-06:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '5bcd6cb7-925d-4a3c-b2fc-6744e75edbe4' User entered '10 Mar 2021 00:03:41'	System	17 Mar 2021 05:02:40
	System	17 Mar 2021 05:02:40

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-03-17T00:02:19-05:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '09154234-86a3-4e8f-81b5-4065c21bee71'	System	26 Mar 2021 17:00:17
User entered 'No (N)'	System	26 Mar 2021 17:00:17

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-03-17T00:02:20-05:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '09154234-86a3-4e8f-81b5-4065c21bee71' User entered 'No (N)'	System	26 Mar 2021 17:00:17
	System	26 Mar 2021 17:00:17

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-03-17T00:02:22-05:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '09154234-86a3-4e8f-81b5-4065c21bee71' User entered '17 Mar 2021 00:02:22'	System	26 Mar 2021 17:00:17
	System	26 Mar 2021 17:00:17

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-03-26T12:00:32-05:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'c19620aa-92c5-4e24-874d-33320851d03e' User entered 'No (N)'	System	26 Mar 2021 17:00:49
	System	26 Mar 2021 17:00:49

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-03-26T12:00:33-05:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'c19620aa-92c5-4e24-874d-33320851d03e' User entered 'No (N)'	System	26 Mar 2021 17:00:49

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-03-26T12:00:35-05:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'c19620aa-92c5-4e24-874d-33320851d03e' User entered '26 Mar 2021 12:00:35'	System	26 Mar 2021 17:00:49
	System	26 Mar 2021 17:00:49

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-03-31T00:02:25-05:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'd0f553b5-ca19-446d-85aa-1c4017b36856'	System	31 Mar 2021 05:02:39
User entered 'No (N)'	System	31 Mar 2021 05:02:39

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-03-31T00:02:27-05:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'd0f553b5-ca19-446d-85aa-1c4017b36856'	System	31 Mar 2021 05:02:39
User entered 'No (N)'	System	31 Mar 2021 05:02:39

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-03-31T00:02:29-05:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'd0f553b5-ca19-446d-85aa-1c4017b36856' User entered '31 Mar 2021 00:02:29'	System	31 Mar 2021 05:02:39
	System	31 Mar 2021 05:02:39

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-04-07T17:54:25-05:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '9a6c95ab-490f-408f-bb0b-6a9ffb0fec4d' User entered 'No (N)'	System	07 Apr 2021 22:54:33

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-04-07T17:54:26-05:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '9a6c95ab-490f-408f-bb0b-6a9ffb0fec4d' User entered 'No (N)'	System	07 Apr 2021 22:54:33

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-04-07T17:54:28-05:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '9a6c95ab-490f-408f-bb0b-6a9ffb0fec4d' User entered '07 Apr 2021 17:54:28'	System	07 Apr 2021 22:54:33
	System	07 Apr 2021 22:54:33

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-04-14T11:18:28-05:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '0cf5d51e-e162-4c62-babc-b53d31319bbc' User entered 'No (N)'	System	14 Apr 2021 17:37:58

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-04-14T11:18:30-05:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '0cf5d51e-e162-4c62-babc-b53d31319bbc' User entered 'No (N)'	System	14 Apr 2021 17:37:58

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-04-14T11:18:32-05:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '0cf5d51e-e162-4c62-babc-b53d31319bbc' User entered '14 Apr 2021 11:18:32'	System	14 Apr 2021 17:37:58
	System	14 Apr 2021 17:37:58

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-04-24T18:09:09-05:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '94c69531-4d29-4035-b7d3-8b3357a7ace9' User entered 'No (N)'	System	24 Apr 2021 23:09:17
	System	24 Apr 2021 23:09:17

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-04-24T18:09:10-05:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '94c69531-4d29-4035-b7d3-8b3357a7ace9' User entered 'No (N)'	System	24 Apr 2021 23:09:17

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-04-24T18:09:13-05:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '94c69531-4d29-4035-b7d3-8b3357a7ace9' User entered '24 Apr 2021 18:09:13'	System	24 Apr 2021 23:09:17
	System	24 Apr 2021 23:09:17

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-04-28T01:29:47-05:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'cb5dd316-5e1d-4396-a957-038500eea8a2' User entered 'No (N)'	System	28 Apr 2021 23:23:24
	System	28 Apr 2021 23:23:24

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-04-28T01:29:48-05:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'cb5dd316-5e1d-4396-a957-038500eea8a2' User entered 'No (N)'	System	28 Apr 2021 23:23:24

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-04-28T01:29:50-05:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: 'cb5dd316-5e1d-4396-a957-038500eea8a2'	System	28 Apr 2021 23:23:24
User entered '28 Apr 2021 01:29:50'	System	28 Apr 2021 23:23:24

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 01:47:21

US3572076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:17:25

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:47:21
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 01:47:21

US3572076

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:17:25

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-03-03T00:01:31-06:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '9f687ac6-2e28-4541-8ecb-41a0fdbaf183'	System	10 Mar 2021 06:03:38
User entered 'No (N)'	System	10 Mar 2021 06:03:38

US3572076

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:17:25

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:29:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AB369D5-6D85-43E5-AE2E-582F8311BDBB)', Time: '2021-03-03T00:01:38-06:00', User OID: 'PatientReportedOutcome (US3572076)', ODM File OID: '9f687ac6-2e28-4541-8ecb-41a0fdbaf183'	System	10 Mar 2021 06:03:38
User entered '03 Mar 2021 06:01:38'	System	10 Mar 2021 06:03:38

US3572076

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:12:37
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	24 Nov 2020 16:48:54

US3572076

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:12:37
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 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)	21 Dec 2020 08:21:02
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	Jessica McDowell (b) (4)	17 Dec 2020 21:44:55
answered with 'previously unable to reach. number was disconnected. subject called site today and updated number' (Site from System).	(b) (4)	
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	17 Dec 2020 21:44:16
User entered '17 Dec 2020' reason for change: Data Entry Error	Jessica McDowell (b) (4)	17 Dec 2020 21:44:16
User entered '19 Nov 2020'	Jackie Ziegler (b) (4)	24 Nov 2020 16:48:54
	(b) (4)	

US3572076

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:12:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Jessica McDowell (b) (4)	17 Dec 2020 21:44:16
User entered 'Contact Not Made (CONTACT NOT	(b) (4)	
MADE)'	Jackie Ziegler (b) (4)	24 Nov 2020 16:48:54
	(b) (4)	

US3572076

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:12:37
User entered 'previously unable to reach. number was disconnected. subject called site today and updated number' reason for change: Data Entry Error	(b) (4)	
User entered empty; reason for change Data Entry Error	Jessica McDowell (b) (4)	17 Dec 2020 21:45:02
User entered 'numerous attempts made to reach patient. phone goes straight to voicemail and voicemail is not set up. texts and email also sent. email undeliverable'	(b) (4)	
	Jessica McDowell (b) (4)	17 Dec 2020 21:44:16
	(b) (4)	
	Jackie Ziegler (b) (4)	24 Nov 2020 16:48:54
	(b) (4)	

US3572076

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:12:37
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	24 Nov 2020 16:47:56

US3572076

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:32:49
User entered 'l'	System	24 Nov 2020 16:47:56

US3572076

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:14
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 01 SEP 2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the sample has been collected and update the details under appropriate visit or provide clarification, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 12:03:49
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 01 SEP 2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the sample has been collected and update the details under appropriate visit or provide clarification, thank you.' answered with 'Sample collected on 01SEP2020 was for Unscheduled Visit. Unscheduled visit has been recorded in EDC. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 03:59:55
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 01 SEP 2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the sample has been collected and update the details under appropriate visit or provide clarification, thank you.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 11:00:46
Data hard unlocked.	(b) (4), (b) (6)	05 Jan 2021 11:00:29
Data hard locked.	(b) (4), (b) (6)	05 Jan 2021 11:00:25
User entered 'Yes (Y)'	Jackie Ziegler (b) (4) (b) (4)	21 Dec 2020 17:37:08

US3572076

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:14
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '21 Dec 2020'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	21 Dec 2020 17:37:08

US3572076

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:14
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jackie Ziegler (b) (4)	21 Dec 2020 17:37:08

US3572076

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:14
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	21 Dec 2020 17:37:08
	(b) (4)	

US3572076

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:14
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	21 Dec 2020 17:37:14

US3572076

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:14
User entered 'l'	System	21 Dec 2020 17:37:14

US3572076

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:14
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User closed query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample collected on 26JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' (Site from DM).	(b) (4) (u) (4), (b) (6)	24 Feb 2021 12:30:44
Query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample collected on 26JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' answered with 'sample collected on 26Jan21 entered into EDC for PDV' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 21:54:32
User opened query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample collected on 26JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 14:32:37
User entered 'Yes (Y)'	Jackie Ziegler (b) (4) (b) (4)	19 Jan 2021 19:57:33

US3572076

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:14
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User closed query 'Per GCL Lab Recon: Immuno: Per GCL, there is an Immuno sample collected on 26 JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 12:30:49
' (Site from DM). Query 'Per GCL Lab Recon: Immuno: Per GCL, there is an Immuno sample collected on 26 JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.	(b) (4), (b) (6)	22 Feb 2021 21:54:50
' answered with 'sample collected on 26Jan21 entered into EDC for PDV' (Site from DM). User opened query 'Per GCL Lab Recon: Immuno: Per GCL, there is an Immuno sample collected on 26 JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.	(b) (4), (b) (6)	18 Feb 2021 14:33:13
' (Site from DM). User entered '19 Jan 2021'	Jackie Ziegler (b) (4) (b) (4)	19 Jan 2021 19:57:33

US3572076

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:14
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jackie Ziegler (b) (4)	19 Jan 2021 19:57:33

US3572076

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:14
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	19 Jan 2021 19:57:33

US3572076

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:14
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	19 Jan 2021 19:57:37

US3572076

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:14
User entered 'l'	System	19 Jan 2021 19:57:37

US3572076

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:14
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	18 Feb 2021 20:22:07

US3572076

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:14
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '18 Feb 2021'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	18 Feb 2021 20:22:07

US3572076

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:14
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jackie Ziegler (b) (4)	18 Feb 2021 20:22:07

US3572076

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:14
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	18 Feb 2021 20:22:07

US3572076

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:14
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	18 Feb 2021 20:22:13

US3572076

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:54:14
User entered 'l'	System	18 Feb 2021 20:22:13

US3572076

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:04:45
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	20 Apr 2021 14:48:07

US3572076

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 14:48:07

US3572076

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:29
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Apr 2021 18:05:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 14:48:44

US3572076

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	29 Apr 2021 10:22:40
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:29
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Apr 2021 18:05:24
Query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Subject was non responsive to safety nurse. Safety nurse was able to make contact on this date. ' (Site from System).	(b) (4), (b) (6)	28 Apr 2021 17:12:16
User opened query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	26 Apr 2021 22:11:08
User entered '26 Apr 2021' reason for change: New Information	(b) (4), (b) (6)	26 Apr 2021 22:11:08
User entered '22 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 14:28:28
User entered '20 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 14:48:44

US3572076

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:29
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Apr 2021 18:05:24
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	(b) (4), (b) (6)	26 Apr 2021 22:11:08
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	20 Apr 2021 14:48:44

US3572076

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 22:40:29
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Apr 2021 18:05:24
User entered empty; reason for change New Information	(b) (4), (b) (6)	26 Apr 2021 22:11:08
User entered 'Unable to reach patient consecutively voicemail left.'	(b) (4), (b) (6)	20 Apr 2021 14:48:44

US3572076

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:04:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	26 Apr 2021 22:11:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Apr 2021 22:11:25
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	26 Apr 2021 22:11:25
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Apr 2021 22:11:14
User entered empty.	(b) (4), (b) (6)	26 Apr 2021 22:11:14

US3572076

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'l'	System	26 Apr 2021 22:11:25
User entered empty.	System	26 Apr 2021 22:11:14

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:17:25

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:46
User entered '1 Sep 2020'	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:18:45

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:17:25

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:46
User entered '16:00'	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:18:45

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:17:25

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User entered '1 Sep 2020 16:00'	System	09 Apr 2021 20:18:45

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:17:25

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:46
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:18:45

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:17:25

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:46
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:18:45

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:17:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:46
User entered 'Day 1 (Day 1)'	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:19:28

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:17:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:46
User entered '1 Sep 2020'	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:19:28

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:17:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:46
User entered 'I'	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:19:28

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:17:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:46
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:19:28

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:17:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User entered empty.	System	09 Apr 2021 20:19:28

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:17:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:46
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:19:28

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:17:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:46
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:19:28

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:17:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:46
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:19:28

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:17:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:46
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:19:28

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:17:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:46
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:19:28

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:17:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:46
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:19:28

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:17:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:46
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:19:28

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:17:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:46
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:19:28

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:17:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:46
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:19:28

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:17:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:46
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:19:28

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:17:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:46
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:19:28

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:17:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:46
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:19:28

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:17:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:46
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:19:28

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:17:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:46
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:19:28

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:17:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:46
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:19:28

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:17:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:46
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:19:28

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:17:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:46
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:19:28

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:17:25

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:44
User entered '1 Sep 2020'	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:21:55

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:17:25

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:44
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:21:55

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:17:25

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:44
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:21:55

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:17:25

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:44
User entered '1 Sep 2020'	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:21:55

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:17:25

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:44
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 20:21:55

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:17:25

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:44
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:21:55

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:17:25

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:44
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:21:55

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:17:25

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:44
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:21:55

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:17:25

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:44
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:21:55

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:17:25

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User entered '0'	System	09 Apr 2021 20:21:55

US3572076

Folder: Covid-19 Assessment 01 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:17:25

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:33
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:06:46
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	09 Apr 2021 20:22:13

US3572076

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:17:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	26 Feb 2021 17:51:18

US3572076

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:17:25

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User closed query 'Per GCL Lab Recon: it appears GCL has a Saliva Sample with date 01SEP2020 ; however there is no record in EDC. Please reconcile or clarify. ?' (Site from DM).	(b) (4) (u) (4), (b) (6)	12 Mar 2021 10:53:42
Query 'Per GCL Lab Recon: it appears GCL has a Saliva Sample with date 01SEP2020 ; however there is no record in EDC. Please reconcile or clarify. ?' answered with 'saliva sample dated 01sep2020 was collected for same visit Day 1 ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 16:02:11
User opened query 'Per GCL Lab Recon: it appears GCL has a Saliva Sample with date 01SEP2020 ; however there is no record in EDC. Please reconcile or clarify. ?' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 05:18:11
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 17:51:18

US3572076

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:17:25

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 17:51:18

US3572076

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:17:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	26 Feb 2021 17:51:18

US3572076

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:17:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 17:51:18

US3572076

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:17:25

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 17:51:18

US3572076

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:17:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	26 Feb 2021 17:51:18

US3572076

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:17:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 17:51:18

US3572076

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:17:25

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 17:51:18

US3572076

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:17:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	26 Feb 2021 17:51:18

US3572076

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:17:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 17:51:18

US3572076

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:17:25

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 17:51:18

US3572076

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:17:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	26 Feb 2021 17:51:18

US3572076

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:17:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 17:51:18

US3572076

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:17:25

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 17:51:18

US3572076

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:17:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	26 Feb 2021 17:51:18

US3572076

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:17:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 17:51:18

US3572076

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:17:25

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 17:51:18

US3572076

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:17:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	26 Feb 2021 17:51:18

US3572076

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:17:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 17:51:18

US3572076

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:17:25

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 17:51:18

US3572076

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:17:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Maria Candelario (b) (4) (b) (4)	13 Apr 2021 00:22:24

US3572076

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:17:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
	(b) (4)	
User entered 'No (N)'	Maria Candelario (b) (4)	13 Apr 2021 00:22:24
	(b) (4)	

US3572076

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:17:25

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
	(b) (4)	
User entered empty.	Maria Candelario (b) (4)	13 Apr 2021 00:22:24
	(b) (4)	

US3572076

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:17:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Maria Candelario (b) (4) (b) (4)	13 Apr 2021 00:22:24

US3572076

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:17:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
	(b) (4)	
User entered 'No (N)'	Maria Candelario (b) (4)	13 Apr 2021 00:22:24
	(b) (4)	

US3572076

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:17:25

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
	(b) (4)	
User entered empty.	Maria Candelario (b) (4)	13 Apr 2021 00:22:24
	(b) (4)	

US3572076

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:17:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Maria Candelario (b) (4) (b) (4)	13 Apr 2021 00:22:24

US3572076

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:17:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
	(b) (4)	
User entered 'No (N)'	Maria Candelario (b) (4)	13 Apr 2021 00:22:24
	(b) (4)	

US3572076

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:17:25

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
	(b) (4)	
User entered empty.	Maria Candelario (b) (4)	13 Apr 2021 00:22:24
	(b) (4)	

US3572076

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:17:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Maria Candelario (b) (4) (b) (4)	13 Apr 2021 00:22:24

US3572076

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:17:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
	(b) (4)	
User entered 'No (N)'	Maria Candelario (b) (4)	13 Apr 2021 00:22:24
	(b) (4)	

US3572076

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:17:25

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
	(b) (4)	
User entered empty.	Maria Candelario (b) (4)	13 Apr 2021 00:22:24
	(b) (4)	

US3572076

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:17:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Maria Candelario (b) (4) (b) (4)	13 Apr 2021 00:22:24

US3572076

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:17:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
	(b) (4)	
User entered 'No (N)'	Maria Candelario (b) (4)	13 Apr 2021 00:22:24
	(b) (4)	

US3572076

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:17:25

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
	(b) (4)	
User entered empty.	Maria Candelario (b) (4)	13 Apr 2021 00:22:24
	(b) (4)	

US3572076

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:17:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Maria Candelario (b) (4) (b) (4)	13 Apr 2021 00:22:24

US3572076

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:17:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
	(b) (4)	
User entered 'No (N)'	Maria Candelario (b) (4)	13 Apr 2021 00:22:24
	(b) (4)	

US3572076

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:17:25

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
	(b) (4)	
User entered empty.	Maria Candelario (b) (4)	13 Apr 2021 00:22:24
	(b) (4)	

US3572076

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:17:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Maria Candelario (b) (4) (b) (4)	13 Apr 2021 00:22:24

US3572076

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:17:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
	(b) (4)	
User entered 'No (N)'	Maria Candelario (b) (4)	13 Apr 2021 00:22:24
	(b) (4)	

US3572076

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:17:25

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
	(b) (4)	
User entered empty.	Maria Candelario (b) (4)	13 Apr 2021 00:22:24
	(b) (4)	

US3572076

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 01-Sep-2020 (Accession No: 1F621022250) is reported as an Illness Visit sample in PPD Central Labs however, data is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating Swab data in the COVID Diagnostic form. Else clarify.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 11:18:19
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 01-Sep-2020 (Accession No: 1F621022250) is reported as an Illness Visit sample in PPD Central Labs however, data is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating Swab data in the COVID Diagnostic form. Else clarify.' answered with 'information updated' (Site from DM).	(b) (4) (u) (4), (b) (6)	13 Apr 2021 21:52:27
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 01-Sep-2020 (Accession No: 1F621022250) is reported as an Illness Visit sample in PPD Central Labs however, data is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating Swab data in the COVID Diagnostic form. Else clarify.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 11:18:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 19:37:12

US3572076

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User closed query 'Per GCL Lab Recon: it appears GCL has a Saliva Sample with date 01SEP2020 ; however there is no record in EDC. Please reconcile or clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 05:17:27
Query 'Per GCL Lab Recon: it appears GCL has a Saliva Sample with date 01SEP2020 ; however there is no record in EDC. Please reconcile or clarify.'	(b) (4), (b) (6)	09 Mar 2021 21:17:43
answered with 'updated' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 08:56:58
User opened query 'Per GCL Lab Recon: it appears GCL has a Saliva Sample with date 01SEP2020 ; however there is no record in EDC. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 19:37:12
User entered '01 Sep 2020'	(b) (4), (b) (6)	

US3572076

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[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 19:18:12
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered 'Clinic (Clinic)'	(b) (4) (u) (4), (b) (6)	16 Feb 2021 19:37:12

US3572076

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User entered 'SICKD1'	System	16 Feb 2021 19:37:12

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	16 Feb 2021 19:41:03

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '01 Sep 2020'	(b) (4) (u) (4), (b) (6)	16 Feb 2021 19:41:03

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	18 Feb 2021 02:48:02
Query 'Data is required. Please provide.' answered with 'Not in source. ' (Site from System).	(b) (4), (b) (6)	16 Feb 2021 19:41:52
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Feb 2021 19:41:03
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 19:41:03

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User entered empty.	System	16 Feb 2021 19:41:03

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '97.9' F	(b) (4) (u) (4), (b) (6)	16 Feb 2021 19:41:03

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Other (Other)'	(b) (4) (u) (4), (b) (6)	16 Feb 2021 19:41:03

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'temporal'	(b) (4) (u) (4), (b) (6)	16 Feb 2021 19:41:03

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '89'	(b) (4) (u) (4), (b) (6)	16 Feb 2021 19:41:03

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User entered 'bpm'	System	16 Feb 2021 19:41:03

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '20'	(b) (4) (u) (4), (b) (6)	16 Feb 2021 19:41:03

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User entered 'breaths/min'	System	16 Feb 2021 19:41:03

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '108'	(b) (4) (u) (4), (b) (6)	16 Feb 2021 19:41:03

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User entered 'mmHg'	System	16 Feb 2021 19:41:03

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
Signature has been broken indirectly.	(b) (4)	13 Apr 2021 00:20:17
User signature succeeded.	System	13 Apr 2021 00:20:17
	Milton Haber (b) (4)	03 Apr 2021 04:23:30
	(b) (4)	
User entered '69'	(b) (4), (b) (6)	16 Feb 2021 19:41:03

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User entered 'mmHg'	System	16 Feb 2021 19:41:03

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12

US3572076

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	16 Feb 2021 19:42:59

US3572076

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '01 Sep 2020'	(b) (4) (u) (4), (b) (6)	16 Feb 2021 19:42:59

US3572076

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 08:17:25

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	16 Feb 2021 19:45:02

US3572076

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 08:17:25

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User closed query 'Per GCL Lab Recon: SARS-COV2: Per SARS-COV2 Preclarus report, Sample dated 01 SEP 2020 is reported under ILLNESS VISIT DAY 1 in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please confirm the correct Visit in the response and update accordingly in Preclarus PPD portal, so that there is a matching of data between EDC & GCL records. Thank you.' (Site from DM). Query 'Per GCL Lab Recon: SARS-COV2: Per SARS-COV2 Preclarus report, Sample dated 01 SEP 2020 is reported under ILLNESS VISIT DAY 1 in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please confirm the correct Visit in the response and update accordingly in Preclarus PPD portal, so that there is a matching of data between EDC & GCL records. Thank you.' answered with 'a DCF has been submitted to PPD for visit change. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 07:21:53
User opened query 'Per GCL Lab Recon: SARS-COV2: Per SARS-COV2 Preclarus report, Sample dated 01 SEP 2020 is reported under ILLNESS VISIT DAY 1 in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please confirm the correct Visit in the response and update accordingly in Preclarus PPD portal, so that there is a matching of data between EDC & GCL records. Thank you.' (Site from DM). User entered '01 Sep 2020'	(b) (4), (b) (6)	03 Mar 2021 23:15:03
	(b) (4), (b) (6)	24 Feb 2021 15:25:20
	(b) (4), (b) (6)	16 Feb 2021 19:45:02

US3572076

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4)	13 Apr 2021 00:20:17
	(b) (4)	

US3572076

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered empty.	(b) (4) Maria Candelario (b) (4)	13 Apr 2021 00:20:17

US3572076

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[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 19:18:12
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered empty.	(b) (4) Maria Candelario (b) (4)	13 Apr 2021 00:20:17
	(b) (4)	

US3572076

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User entered 'SICKD1'	System	13 Apr 2021 00:20:17

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4)	13 Apr 2021 00:21:21

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered empty.	(b) (4) Maria Candelario (b) (4)	13 Apr 2021 00:21:21

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered empty.	(b) (4) Maria Candelario (b) (4)	13 Apr 2021 00:21:21

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User entered empty.	System	13 Apr 2021 00:21:21

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered empty.	(b) (4) Maria Candelario (b) (4)	13 Apr 2021 00:21:21
	(b) (4)	

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered empty.	(b) (4) Maria Candelario (b) (4)	13 Apr 2021 00:21:21

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered empty.	(b) (4) Maria Candelario (b) (4)	13 Apr 2021 00:21:21
	(b) (4)	

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered empty.	(b) (4) Maria Candelario (b) (4)	13 Apr 2021 00:21:21
	(b) (4)	

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User entered empty.	System	13 Apr 2021 00:21:21

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4) (b) (4)	13 Apr 2021 04:31:38
User entered empty.	Maria Candelario (b) (4) (b) (4)	13 Apr 2021 00:21:21

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User entered empty.	System	13 Apr 2021 00:21:21

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered empty.	(b) (4) Maria Candelario (b) (4)	13 Apr 2021 00:21:21

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User entered empty.	System	13 Apr 2021 00:21:21

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered empty.	(b) (4) Maria Candelario (b) (4)	13 Apr 2021 00:21:21

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User entered empty.	System	13 Apr 2021 00:21:21

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12

US3572076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12

US3572076

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4)	13 Apr 2021 00:21:02

US3572076

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:25

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered empty.	(b) (4) Maria Candelario (b) (4)	13 Apr 2021 00:21:02

US3572076

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 08:17:25

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered 'Yes (Y)'	(b) (4) Maria Candelario (b) (4)	13 Apr 2021 00:20:53

US3572076

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 08:17:25

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:18:12
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered empty.	(b) (4) Maria Candelario (b) (4)	13 Apr 2021 00:20:53

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 17:49:35

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 17:49:35

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 17:49:35

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	26 Feb 2021 17:49:35

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 17:49:48

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 17:49:48

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 17:49:48

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 17:49:48

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 17:49:48

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 17:49:48

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 17:49:48

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 17:49:48

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 17:49:48

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 17:49:48

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 17:49:48

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 17:49:48

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 17:49:48

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 17:49:48

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 17:49:48

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:25

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 17:49:59

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:25

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 17:49:59

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 08:17:25

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 17:50:08

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 08:17:25

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 17:50:08

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
	(b) (4)	
User entered 'No (N)'	Maria Candelario (b) (4)	13 Apr 2021 00:22:09
	(b) (4)	

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
	(b) (4)	
User entered empty.	Maria Candelario (b) (4)	13 Apr 2021 00:22:09
	(b) (4)	

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
	(b) (4)	
User entered empty.	Maria Candelario (b) (4)	13 Apr 2021 00:22:09
	(b) (4)	

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	13 Apr 2021 00:22:09

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4)	13 Apr 2021 00:21:58
	(b) (4)	

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered empty.	(b) (4)	
	Maria Candelario (b) (4)	13 Apr 2021 00:21:58
	(b) (4)	

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
	(b) (4)	
User entered empty.	Maria Candelario (b) (4)	13 Apr 2021 00:21:58
	(b) (4)	

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 00:21:58

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
	(b) (4)	
User entered empty.	Maria Candelario (b) (4)	13 Apr 2021 00:21:58
	(b) (4)	

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
	(b) (4)	
User entered empty.	Maria Candelario (b) (4)	13 Apr 2021 00:21:58
	(b) (4)	

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
	(b) (4)	
User entered empty.	Maria Candelario (b) (4)	13 Apr 2021 00:21:58
	(b) (4)	

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered empty.	(b) (4)	
	Maria Candelario (b) (4)	13 Apr 2021 00:21:58
	(b) (4)	

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 00:21:58

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
	(b) (4)	
User entered empty.	Maria Candelario (b) (4)	13 Apr 2021 00:21:58
	(b) (4)	

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 00:21:58

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered empty.	(b) (4)	
	Maria Candelario (b) (4)	13 Apr 2021 00:21:58
	(b) (4)	

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 00:21:58

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered empty.	(b) (4)	
	Maria Candelario (b) (4)	13 Apr 2021 00:21:58
	(b) (4)	

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:17:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 00:21:58

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:25

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4)	13 Apr 2021 00:21:47
	(b) (4)	

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
	(b) (4)	
User entered empty.	Maria Candelario (b) (4)	13 Apr 2021 00:21:47
	(b) (4)	

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 08:17:25

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4)	13 Apr 2021 00:21:31
	(b) (4)	

US3572076

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 08:17:25

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered empty.	(b) (4) Maria Candelario (b) (4)	13 Apr 2021 00:21:31
	(b) (4)	

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 21:52:21

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '26 Jan 2021'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 21:52:21

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[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 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:52:21

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered 'UNBLND_DECIDE'	System	22 Feb 2021 21:52:21

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:17:25

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:52:54

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:17:25

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:48:29

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:17:25

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:52:54

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:17:25

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:48:29

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:17:25

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '26 Jan 2021'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 21:52:54

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:17:25

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:52:54

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:17:25

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:52:54

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:17:25

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:52:54

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:17:25

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:52:54

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:17:25

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered 'I'	System	22 Feb 2021 21:52:54

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:17:25

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered 'I'	System	22 Feb 2021 21:52:54

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:25

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:25

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered empty.	System	26 Feb 2021 03:00:33
DataPoint set to visible.	System	22 Feb 2021 21:52:54

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:25

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:25

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered empty.	System	26 Feb 2021 03:00:33
DataPoint set to visible.	System	22 Feb 2021 21:52:54

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '17:57'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered '25 Feb 2021 17:57'	System	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '97.2' F	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'TEMPORAL'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '76'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered 'bpm'	System	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '18'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered 'breaths/min'	System	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '94'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered 'mmHg'	System	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 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)	01 Mar 2021 07:54:26
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 03:00:41
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		26 Feb 2021 03:00:33
User entered '59'	(b) (4), (b) (6)	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered 'mmHg'	System	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:25

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:17:25

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered empty.	System	26 Feb 2021 03:00:33
DataPoint set to visible.	System	22 Feb 2021 21:52:54

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '18:56'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered '25 Feb 2021 18:56'	System	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'TEMPORAL'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '78'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered 'bpm'	System	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '18'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered 'breaths/min'	System	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '103'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered 'mmHg'	System	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '70'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered 'mmHg'	System	26 Feb 2021 03:00:33

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:00:47

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:00:47

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:01:07

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:01:07

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:01:07

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:01:07

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:01:07

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:01:07

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:01:07

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered empty.	System	26 Feb 2021 03:01:07

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:01:23

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:01:23

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 03:01:23

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered 'mRNA-1273'	System	26 Feb 2021 03:01:23
DataPoint set to visible.	System	22 Feb 2021 21:52:54

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:01:23

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '18:26'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:01:23

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered '25 Feb 2021 18:26'	System	26 Feb 2021 03:01:23

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:01:23

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered 'ONCE'	System	26 Feb 2021 03:01:23

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered 'INTRAMUSCULAR'	System	26 Feb 2021 03:01:23

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 21:53:21

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19MAR2021 is recorded under Visit 04 Day 209 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC per CCGs V.5.0 page 34-35 in Immunogenicity Assessment eCRF under Visit 04 Day 209 folder as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 09:10:14
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19MAR2021 is recorded under Visit 04 Day 209 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC per CCGs V.5.0 page 34-35 in Immunogenicity Assessment eCRF under Visit 04 Day 209 folder as appropriate. Else Clarify, Thank you' answered with 'DCF submitted to PPD, subject did not have Visit 4' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 17:42:14
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19MAR2021 is recorded under Visit 04 Day 209 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC per CCGs V.5.0 page 34-35 in Immunogenicity Assessment eCRF under Visit 04 Day 209 folder as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 10:24:28
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '26 Jan 2021'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 21:53:21

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '10:42'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 21:53:21

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:17:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered '26 Jan 2021 10:42'	System	22 Feb 2021 21:53:21

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:17:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 21:53:41

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:17:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '26 Jan 2021'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 21:53:41

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:17:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '10:29'	(b) (4) (u) (4), (b) (6)	22 Feb 2021 21:53:41

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:17:25

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered '26 Jan 2021 10:29'	System	22 Feb 2021 21:53:41

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 03:01:30

US3572076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:59
User entered 'I'	System	26 Feb 2021 03:01:30

US3572076

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:14
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	04 Mar 2021 21:57:25

US3572076

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:14
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '4 Mar 2021'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	04 Mar 2021 21:57:25

US3572076

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:14
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jackie Ziegler (b) (4)	04 Mar 2021 21:57:25

US3572076

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:17:25

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:14
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	04 Mar 2021 21:57:25

US3572076

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:14
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	04 Mar 2021 21:57:29

US3572076

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:14
User entered 'l'	System	04 Mar 2021 21:57:29

US3572076

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:14
User entered 'I'	System	04 Mar 2021 21:57:29
DataPoint set to visible.	System	04 Mar 2021 21:57:29

US3572076

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:14:23

US3572076

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered '8 Apr 2021'	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:14:23

US3572076

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered 'Clinic (Clinic)'	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:14:23

US3572076

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:17:25

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	13 Apr 2021 14:14:23

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered '8 Apr 2021'	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered '14:40'	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '8 Apr 2021 14:40'	System	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered '97.5' F	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered 'Other (Other)'	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered 'TEMPORAL'	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered '84'	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered '18'	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered '106'	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered '62'	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:17:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered empty.	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered empty.	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered empty.	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered empty.	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered empty.	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered empty.	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered empty.	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered empty.	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered empty.	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:17:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 14:15:46

US3572076

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:25

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:15:54

US3572076

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:17:25

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered empty.	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:15:54

US3572076

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:16:21

US3572076

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered '8 Apr 2021'	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:16:21

US3572076

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Test performed](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered 'Urine (URINE)'	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:16:21

US3572076

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Result](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User closed query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	(b) (4) (u) (4), (b) (6)	14 Apr 2021 05:34:14
Query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' answered with 'FORM SUBMITTED' (Site from System).	(b) (4), (b) (6)	13 Apr 2021 14:16:53
User opened query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	System	13 Apr 2021 14:16:21
User entered 'Positive (POSITIVE)'	(b) (4), (b) (6)	13 Apr 2021 14:16:21

US3572076

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:16:21

US3572076

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Collection date](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered empty.	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:16:21

US3572076

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Collection time](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered empty.	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:16:21

US3572076

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 08:17:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 14:16:21

US3572076

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:17:22

US3572076

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered 'Pregnancy (PREGNANCY)'	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:17:22

US3572076

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered empty.	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:17:22

US3572076

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 14:17:22
DataPoint set to visible.	System	04 Mar 2021 21:57:29

US3572076

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered empty.	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:17:22

US3572076

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered empty.	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:17:22

US3572076

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 14:17:22

US3572076

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered empty.	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:17:22

US3572076

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 14:17:22

US3572076

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:17:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 14:17:22

US3572076

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	15 Apr 2021 19:13:52
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:17:26

US3572076

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:17:25

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 14:17:26

US3572076

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:17:25

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:55:38
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Yes (Y)'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 19:58:20

US3572076

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42

US3572076

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 05:55:08
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'Pt was contacted and brought in for visit' (Site from DM).	Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 19:53:43
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 10:50:35
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Throat irritation, LLT: Throat irritation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 11:55:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 11:55:49
Data point term sent to Coder	System	31 Aug 2020 20:10:17
User entered 'Sore/Dry throat'	Jasmine Ali (b) (4) (b) (4)	31 Aug 2020 20:09:52

US3572076

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:09:52

US3572076

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	07 Oct 2020 13:41:15
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' answered with 'data updated' (Site from DM).	Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:22:45
User entered 'No (N)' reason for change: Data Entry Error	Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:22:31
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 03:31:09
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	31 Aug 2020 20:09:52

US3572076

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:09:52

US3572076

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '29 Aug 2020'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:09:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:09:52

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User entered empty.	System	31 Aug 2020 20:09:52

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Jasmine Ali (b) (4)	09 Sep 2020 15:49:43
User entered 'Yes (Y)'	(b) (4)	
	Jasmine Ali (b) (4)	31 Aug 2020 20:09:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '4 Sep 2020' reason for change: New Information	Jasmine Ali (b) (4)	09 Sep 2020 15:49:43
User entered empty.	Jasmine Ali (b) (4)	31 Aug 2020 20:09:52

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:09:52

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User entered empty.	System	31 Aug 2020 20:09:52

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:09:52

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:09:52

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:09:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:09:52

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:09:52

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:09:52

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:09:52

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:09:52

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:09:52

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:09:52

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:09:52

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:09:52

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Oct 2020 19:55:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 19:55:14
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Alisha Lutat (b) (4)	22 Oct 2020 19:55:14
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	31 Aug 2020 20:09:52
User entered empty.	System	31 Aug 2020 20:09:52
	Jasmine Ali (b) (4)	31 Aug 2020 20:09:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Oct 2020 19:55:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 19:55:14
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Alisha Lutat (b) (4)	22 Oct 2020 19:55:14
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	31 Aug 2020 20:09:52
User entered empty.	System	31 Aug 2020 20:09:52
	Jasmine Ali (b) (4)	31 Aug 2020 20:09:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
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	02 Oct 2020 04:22:31
User entered 'None (NONE)' reason for change: Data Entry Error	System	02 Oct 2020 04:22:31
User opened query 'Data is required. Please complete.' (Site from System).	Alisha Lutat (b) (4)	02 Oct 2020 04:22:31
User entered empty.	(b) (4)	
	System	31 Aug 2020 20:09:52
	Jasmine Ali (b) (4)	31 Aug 2020 20:09:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0' reason for change: New Information	(b) (4)	
	Jasmine Ali (b) (4)	09 Sep 2020 15:49:43
User entered '1'	(b) (4)	
	Jasmine Ali (b) (4)	31 Aug 2020 20:09:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '1' reason for change: New Information	(b) (4)	
	Jasmine Ali (b) (4)	09 Sep 2020 15:49:43
User entered '0'	(b) (4)	
	Jasmine Ali (b) (4)	31 Aug 2020 20:09:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:09:52

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
New Information	Jasmine Ali (b) (4)	09 Sep 2020 15:49:43
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	
	Jasmine Ali (b) (4)	31 Aug 2020 20:09:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

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 18:07:42
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:09:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:09:52

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User entered '0'	System	31 Aug 2020 20:09:52

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42
User entered '0'	System	31 Aug 2020 20:09:52

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:17:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:42

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Epistaxis, LLT: Bleeding nose - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 21:05:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 21:05:37
Data point term sent to Coder	System	31 Aug 2020 20:11:20
User entered 'Bloody nose'	Jasmine Ali (b) (4)	31 Aug 2020 20:11:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	07 Oct 2020 13:43:01
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' answered with 'data updated' (Site from DM).	Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:23:30
User entered 'No (N)' reason for change: Data Entry Error	Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:23:15
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 03:31:15
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	31 Aug 2020 20:11:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '30 Aug 2020'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User entered empty.	System	31 Aug 2020 20:11:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '30 Aug 2020'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User entered empty.	System	31 Aug 2020 20:11:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Oct 2020 19:55:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 19:55:42
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Alisha Lutat (b) (4)	22 Oct 2020 19:55:42
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	31 Aug 2020 20:11:02
User entered empty.	System	31 Aug 2020 20:11:02
	Jasmine Ali (b) (4)	31 Aug 2020 20:11:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Oct 2020 19:55:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 19:55:42
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Alisha Lutat (b) (4)	22 Oct 2020 19:55:42
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	31 Aug 2020 20:11:02
User entered empty.	System	31 Aug 2020 20:11:02
	Jasmine Ali (b) (4)	31 Aug 2020 20:11:02
	(b) (4)	

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Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
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	02 Oct 2020 04:23:15
User entered 'None (NONE)' reason for change: Data Entry Error	Alisha Lutat (b) (4)	02 Oct 2020 04:23:15
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	31 Aug 2020 20:11:02
	Jasmine Ali (b) (4)	31 Aug 2020 20:11:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'l'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	(b) (4)	
	Milton Haber (b) (4)	22 Mar 2021 03:29:47
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jasmine Ali (b) (4)	31 Aug 2020 20:11:02
	(b) (4)	

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Form: Adverse Events (7)

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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 18:07:44
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User entered '0'	System	31 Aug 2020 20:11:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44
User entered '0'	System	31 Aug 2020 20:11:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:17:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:44

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4) (u) (4), (b) (6)	28 Oct 2020 05:54:59
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'Pt was contacted and attended visit. ' (Site from DM).	Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 19:57:08
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 10:50:51
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 20:13:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 20:13:40
Data point term sent to Coder	System	31 Aug 2020 20:12:23
User entered 'Headache'	Jasmine Ali (b) (4) (b) (4)	31 Aug 2020 20:11:36

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:36

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES, however, the corresponding eDiary data for this symptom on this date is noted as NONE. Note that any SAR that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	28 Oct 2020 04:47:16
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES, however, the corresponding eDiary data for this symptom on this date is noted as NONE. Note that any SAR that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification.	Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 19:57:39
' answered with 'data updated ' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error	Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 19:57:27
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES, however, the corresponding eDiary data for this symptom on this date is noted as NONE. Note that any SAR that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 03:31:45
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 03:31:39

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 03:31:21
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	31 Aug 2020 20:11:36

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:36

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '24 Aug 2020'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User closed query 'Per CDM: Please note that the AE start time (00:00) is prior to the exposure time (12:31). If the event occurred prior to the first dose, note that, per CCGs, only SAEs before first dose are recorded. If the event occurred after the first dose, then please update the time as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 03:06:39
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	10 Feb 2021 03:06:37
Query 'Data is required. Please provide.' answered with 'No start time in source.' (Site from System).	(b) (4), (b) (6)	08 Feb 2021 15:28:42
Query 'Per CDM: Please note that the AE start time (00:00) is prior to the exposure time (12:31). If the event occurred prior to the first dose, note that, per CCGs, only SAEs before first dose are recorded. If the event occurred after the first dose, then please update the time as appropriate. Thank you.' answered with 'No start time in source.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 15:28:35
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Feb 2021 15:27:35
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 15:27:35
User opened query 'Per CDM: Please note that the AE start time (00:00) is prior to the exposure time (12:31). If the event occurred prior to the first dose, note that, per CCGs, only SAEs before first dose are recorded. If the event occurred after the first dose, then please update the time as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 18:52:25
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Oct 2020 04:24:06
User entered '00:00' reason for change: Data Entry Error	Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:24:06
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 20:11:36

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jasmine Ali (b) (4) (b) (4)	31 Aug 2020 20:11:36

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User entered empty.	System	08 Feb 2021 15:27:35
User entered '24 Aug 2020 00:00'	System	02 Oct 2020 04:24:06
User entered empty.	System	31 Aug 2020 20:11:36

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'No (N)' reason for change: New Information	(b) (4) Jasmine Ali (b) (4)	09 Sep 2020 15:51:47
User entered 'Yes (Y)'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:36

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '4 Sep 2020' reason for change: New Information	Jasmine Ali (b) (4)	09 Sep 2020 15:51:47
User entered empty.	Jasmine Ali (b) (4)	31 Aug 2020 20:11:36

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Oct 2020 04:24:06
User entered '00:00' reason for change: Data Entry Error	System	02 Oct 2020 04:24:06
User opened query 'Data is required. Please provide.' (Site from System).	Alisha Lutat (b) (4)	02 Oct 2020 04:24:06
User entered empty.	(b) (4)	09 Sep 2020 15:51:47
	Jasmine Ali (b) (4)	31 Aug 2020 20:11:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User entered '4 Sep 2020 00:00'	System	02 Oct 2020 04:24:06
User entered empty.	System	31 Aug 2020 20:11:36

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:36

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:36

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:36

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:36

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:36

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:36

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:36

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:36

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:36

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Oct 2020 19:57:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 19:57:27
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Alisha Lutat (b) (4)	22 Oct 2020 19:57:27
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	31 Aug 2020 20:11:36
User entered empty.	System	31 Aug 2020 20:11:36
	Jasmine Ali (b) (4)	31 Aug 2020 20:11:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Oct 2020 19:57:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 19:57:27
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Alisha Lutat (b) (4)	22 Oct 2020 19:57:27
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	31 Aug 2020 20:11:36
User entered empty.	System	31 Aug 2020 20:11:36
	Jasmine Ali (b) (4)	31 Aug 2020 20:11:36
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
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	02 Oct 2020 04:24:06
User entered 'None (NONE)' reason for change: Data Entry Error	System	02 Oct 2020 04:24:06
User opened query 'Data is required. Please complete.' (Site from System).	Alisha Lutat (b) (4)	02 Oct 2020 04:24:06
User entered empty.	(b) (4)	
	System	31 Aug 2020 20:11:36
	Jasmine Ali (b) (4)	31 Aug 2020 20:11:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'l'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:36

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Folder: Adverse Events

Form: Adverse Events (8)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
New Information	Jasmine Ali (b) (4)	09 Sep 2020 15:51:47
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	
	Jasmine Ali (b) (4)	31 Aug 2020 20:11:36
	(b) (4)	

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Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

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 18:06:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:36

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:11:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User entered '0'	System	31 Aug 2020 20:11:36

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11
User entered '0'	System	31 Aug 2020 20:11:36

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:17:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:11

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:17:25

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:17:25

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User coded data point as SOC: Vascular disorders, HLGT: Vascular disorders NEC, HLT: Peripheral vascular disorders NEC, PT: Hot flush, LLT: Hot flashes - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 20:13:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 20:13:40
Data point term sent to Coder	System	31 Aug 2020 20:12:25
User entered 'Hot flashes'	Jasmine Ali (b) (4)	31 Aug 2020 20:12:04

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:17:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:17:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 06:13:30
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' answered with 'data updated' (Site from DM).	Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:25:02
User entered 'No (N)' reason for change: Data Entry Error	Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 04:24:49
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 03:31:29
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	31 Aug 2020 20:12:04

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:17:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:17:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '24 Aug 2020'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:04

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:17:25

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Oct 2020 04:24:49
User entered '00:00' reason for change: Data Entry Error	System	02 Oct 2020 04:24:49
User opened query 'Data is required. Please provide.' (Site from System).	Alisha Lutat (b) (4)	31 Aug 2020 20:12:04
User entered empty.	(b) (4)	31 Aug 2020 20:12:04

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:17:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User entered '24 Aug 2020 00:00'	System	02 Oct 2020 04:24:49
User entered empty.	System	31 Aug 2020 20:12:04

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:17:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Jasmine Ali (b) (4)	09 Sep 2020 15:52:35
User entered 'Yes (Y)'	(b) (4)	
	Jasmine Ali (b) (4)	31 Aug 2020 20:12:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:17:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '4 Sep 2020' reason for change: New Information	Jasmine Ali (b) (4)	09 Sep 2020 15:52:35
User entered empty.	Jasmine Ali (b) (4)	31 Aug 2020 20:12:04

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:17:25

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Oct 2020 04:24:49
User entered '00:00' reason for change: Data Entry Error	System	02 Oct 2020 04:24:49
User opened query 'Data is required. Please provide.' (Site from System).	Alisha Lutat (b) (4)	02 Oct 2020 04:24:49
User entered empty.	(b) (4)	09 Sep 2020 15:52:35
	Jasmine Ali (b) (4)	31 Aug 2020 20:12:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:17:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User entered '4 Sep 2020 00:00'	System	02 Oct 2020 04:24:49
User entered empty.	System	31 Aug 2020 20:12:04

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:17:25

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:04

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:17:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:04

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:17:25

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:17:25

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:04

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:17:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:04

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:17:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:04

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:17:25

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:04

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:04
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:04

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:04

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:04

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:04

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Oct 2020 19:57:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 19:57:57
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Alisha Lutat (b) (4)	22 Oct 2020 19:57:57
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	31 Aug 2020 20:12:04
User entered empty.	System	31 Aug 2020 20:12:04
	Jasmine Ali (b) (4)	31 Aug 2020 20:12:04
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Oct 2020 19:57:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 19:57:57
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Alisha Lutat (b) (4)	22 Oct 2020 19:57:57
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	31 Aug 2020 20:12:04
User entered empty.	System	31 Aug 2020 20:12:04
	Jasmine Ali (b) (4)	31 Aug 2020 20:12:04
	(b) (4)	

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Folder: Adverse Events

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Generated On: 10 Jun 2021 08:17:25

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
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	02 Oct 2020 04:24:49
User entered 'None (NONE)' reason for change: Data Entry Error	Alisha Lutat (b) (4)	02 Oct 2020 04:24:49
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	31 Aug 2020 20:12:04
	Jasmine Ali (b) (4)	31 Aug 2020 20:12:04
	(b) (4)	

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'l'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:04
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:04

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:04

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
New Information	Jasmine Ali (b) (4)	09 Sep 2020 15:52:35
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	
	Jasmine Ali (b) (4)	31 Aug 2020 20:12:04
	(b) (4)	

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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 18:06:14
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:04

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:04

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:17:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User entered '0'	System	31 Aug 2020 20:12:04

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:17:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:06:14
User entered '0'	System	31 Aug 2020 20:12:04

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Folder: Adverse Events

Form: Adverse Events (9)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	02 May 2021 18:06:14

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11

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Form: Adverse Events (10)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Apocrine and eccrine gland disorders, PT: Hyperhidrosis, LLT: Excess sweating - version MedDRA\23.0.	Coder Import (b) (4)	01 Sep 2020 05:58:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	01 Sep 2020 05:58:47
Data point term sent to Coder	System	31 Aug 2020 20:13:27
User entered 'Excessive sweating'	Jasmine Ali (b) (4)	31 Aug 2020 20:12:29

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:17:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:29

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Folder: Adverse Events

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 04:46:44
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' answered with 'data updated ' (Site from DM).	Alisha Lutat (b) (4)	22 Oct 2020 19:58:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	02 Oct 2020 04:25:51
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 03:32:02
User entered 'Yes (Y)'	Jasmine Ali (b) (4)	31 Aug 2020 20:12:29

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:29

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Folder: Adverse Events

Form: Adverse Events (10)

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '24 Aug 2020'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:29

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:17:25

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Oct 2020 04:25:51
User entered '00:00' reason for change: Data Entry Error	System	02 Oct 2020 04:25:51
User opened query 'Data is required. Please provide.' (Site from System).	Alisha Lutat (b) (4)	31 Aug 2020 20:12:29
User entered empty.	(b) (4)	31 Aug 2020 20:12:29

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User entered '24 Aug 2020 00:00'	System	02 Oct 2020 04:25:51
User entered empty.	System	31 Aug 2020 20:12:29

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'No (N)' reason for change: New Information	(b) (4) Jasmine Ali (b) (4)	09 Sep 2020 15:53:14
User entered 'Yes (Y)'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:29

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '4 Sep 2020' reason for change: New Information	(b) (4)	
	Jasmine Ali (b) (4)	09 Sep 2020 15:53:14
User entered empty.	(b) (4)	
	Jasmine Ali (b) (4)	31 Aug 2020 20:12:29
	(b) (4)	

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Oct 2020 04:25:51
User entered '00:00' reason for change: Data Entry Error	System	02 Oct 2020 04:25:51
User opened query 'Data is required. Please provide.' (Site from System).	Alisha Lutat (b) (4)	02 Oct 2020 04:25:51
User entered empty.	(b) (4)	09 Sep 2020 15:53:14
	Jasmine Ali (b) (4)	31 Aug 2020 20:12:29
	(b) (4)	

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User entered '4 Sep 2020 00:00'	System	02 Oct 2020 04:25:51
User entered empty.	System	31 Aug 2020 20:12:29

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:29
	(b) (4)	

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:29

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:29

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:29

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:29

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:29

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:29

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:29

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:29

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:29

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:29

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:29

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Oct 2020 19:58:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 19:58:51
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Alisha Lutat (b) (4)	22 Oct 2020 19:58:51
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	31 Aug 2020 20:12:29
User entered empty.	System	31 Aug 2020 20:12:29
	Jasmine Ali (b) (4)	31 Aug 2020 20:12:29
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Oct 2020 19:58:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 19:58:51
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Alisha Lutat (b) (4)	22 Oct 2020 19:58:51
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	31 Aug 2020 20:12:29
User entered empty.	System	31 Aug 2020 20:12:29
	Jasmine Ali (b) (4)	31 Aug 2020 20:12:29
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Oct 2020 04:25:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 04:25:51
User entered 'None (NONE)' reason for change: Data Entry Error	Alisha Lutat (b) (4)	02 Oct 2020 04:25:51
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	31 Aug 2020 20:12:29
User entered empty.	System	31 Aug 2020 20:12:29
	Jasmine Ali (b) (4)	31 Aug 2020 20:12:29
	(b) (4)	

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'l'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:17:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:29

US3572076

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:17:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:29

US3572076

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:17:25

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
New Information	Jasmine Ali (b) (4)	09 Sep 2020 15:53:14
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	
	Jasmine Ali (b) (4)	31 Aug 2020 20:12:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:17:25

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 18:07:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:29

US3572076

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:17:25

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:12:29

US3572076

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:17:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User entered '0'	System	31 Aug 2020 20:12:29

US3572076

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:17:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11
User entered '0'	System	31 Aug 2020 20:12:29

US3572076

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 08:17:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:07:11

US3572076

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:17:25

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pruritus, LLT: Injection site itching - version MedDRA\\23.0.	Coder Import (b) (4)	04 Mar 2021 21:59:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Mar 2021 21:59:53
Data point term sent to Coder	System	04 Mar 2021 21:58:39
User entered 'itching at the injection site'	Jackie Ziegler (b) (4)	04 Mar 2021 21:58:10

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:17:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	04 Mar 2021 21:58:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:17:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	04 Mar 2021 21:58:10

US3572076

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:17:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	04 Mar 2021 21:58:10

US3572076

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:17:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '26 Feb 2021'	(b) (4) Jackie Ziegler (b) (4)	04 Mar 2021 21:58:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:17:25

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '10:00'	(b) (4) Jackie Ziegler (b) (4)	04 Mar 2021 21:58:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:17:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '26 Feb 2021 10:00'	System	04 Mar 2021 21:58:10

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:17:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	04 Mar 2021 21:58:10

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:17:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	04 Mar 2021 21:58:10

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:17:25

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	04 Mar 2021 21:58:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:17:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 21:58:10

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:17:25

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Jackie Ziegler (b) (4)	04 Mar 2021 21:58:10

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:17:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	04 Mar 2021 21:58:10

US3572076

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:17:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	04 Mar 2021 21:58:10

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:17:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	04 Mar 2021 21:58:10

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:17:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	04 Mar 2021 21:58:10

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:17:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	04 Mar 2021 21:58:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:17:25

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	04 Mar 2021 21:58:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:17:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	04 Mar 2021 21:58:10
	(b) (4)	

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	04 Mar 2021 21:58:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:17:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	04 Mar 2021 21:58:10

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:17:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	04 Mar 2021 21:58:10

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:17:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	04 Mar 2021 21:58:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:17:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Mar 2021 21:45:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 21:45:16
User entered 'Related (RELATED)' reason for change: New Information	(b) (4), (b) (6)	05 Mar 2021 21:45:16
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Mar 2021 21:58:10
User entered empty.	Jackie Ziegler (b) (4) (b) (4)	04 Mar 2021 21:58:10

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:17:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Mar 2021 21:45:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 21:45:16
User entered 'Related (RELATED)' reason for change: New Information	(b) (4), (b) (6)	05 Mar 2021 21:45:16
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Mar 2021 21:58:10
User entered empty.	Jackie Ziegler (b) (4)	04 Mar 2021 21:58:10
	(b) (4)	

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Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:17:25

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Mar 2021 21:45:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 21:45:16
User entered 'None (NONE)' reason for change: New Information	(b) (4), (b) (6)	05 Mar 2021 21:45:16
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Mar 2021 21:58:10
User entered empty.	Jackie Ziegler (b) (4)	04 Mar 2021 21:58:10
	(b) (4)	

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Folder: Adverse Events

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Generated On: 10 Jun 2021 08:17:25

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'I'	(b) (4) Jackie Ziegler (b) (4)	04 Mar 2021 21:58:10

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:17:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	04 Mar 2021 21:58:10

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Folder: Adverse Events

Form: Adverse Events (11)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '0'	(b) (4) Jackie Ziegler (b) (4)	04 Mar 2021 21:58:10

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Folder: Adverse Events

Form: Adverse Events (11)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Jackie Ziegler (b) (4)	04 Mar 2021 21:58:10

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:17:25

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	04 Mar 2021 21:58:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:29:47
User entered '3 mm x 4 mm' reason for change: New Information	(b) (4) Jackie Ziegler (b) (4)	05 Mar 2021 12:41:46
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	04 Mar 2021 21:58:10

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Folder: Adverse Events

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Mar 2021 21:58:10

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 08:17:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Mar 2021 21:58:10

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 19:28:34
User entered 'USA-US091-2021-mRNA-1273-P301000016'	System	12 Apr 2021 19:28:25
User entered 'New'	(b) (4), (b) (6)	12 Apr 2021 19:28:25

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLGT: Pregnancy, labour, delivery and postpartum conditions, HLT: Normal pregnancy, labour and delivery, PT: Pregnancy, LLT: Pregnancy - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 00:45:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 00:45:53
Data point term sent to Coder	System	09 Apr 2021 00:45:03
User entered 'Pregnancy'	Maria Candelario (b) (4)	09 Apr 2021 00:44:54

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Folder: Adverse Events

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4) (b) (4)	09 Apr 2021 00:44:54

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4) (b) (4)	09 Apr 2021 00:44:54

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4) (b) (4)	09 Apr 2021 00:44:54

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Folder: Adverse Events

Form: Adverse Events (12)

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
	(b) (4)	
User entered '8 Apr 2021'	Maria Candelario (b) (4)	09 Apr 2021 00:44:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered empty.	(b) (4)	
	Maria Candelario (b) (4)	09 Apr 2021 00:44:54
	(b) (4)	

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Folder: Adverse Events

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Generated On: 10 Jun 2021 08:17:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 00:44:54

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:04:45
	(b) (4)	
Signature has been broken.	Maria Candelario (b) (4)	27 Apr 2021 00:34:35
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Maria Candelario (b) (4)	27 Apr 2021 00:34:35
	(b) (4)	
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
	(b) (4)	
User entered 'Yes (Y)'	Maria Candelario (b) (4)	09 Apr 2021 00:44:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). User signature succeeded.	(b) (4), (b) (6)	28 Apr 2021 11:55:12
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'The subject elected to terminate pregnancy without complications' (Site from System). User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). Signature has been broken.	Milton Haber (b) (4) (b) (4) Maria Candelario (b) (4) (b) (4)	28 Apr 2021 10:04:45 27 Apr 2021 00:35:10 27 Apr 2021 00:34:35
User entered '16 Apr 2021' reason for change: Data Entry Error User signature succeeded.	System Maria Candelario (b) (4) (b) (4) Maria Candelario (b) (4) (b) (4) Milton Haber (b) (4) (b) (4)	27 Apr 2021 00:34:35 27 Apr 2021 00:34:35 13 Apr 2021 04:31:38
User entered empty.	Maria Candelario (b) (4) (b) (4)	09 Apr 2021 00:44:54

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Generated On: 10 Jun 2021 08:17:25

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
	(b) (4)	
User entered empty.	Maria Candelario (b) (4)	09 Apr 2021 00:44:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 00:44:54

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'pregancy so severity not applicable' (Site from System).	(b) (4), (b) (6)	12 Apr 2021 10:26:53
	(b) (4), (b) (6)	11 Apr 2021 08:42:49
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 00:44:54
User entered empty.	Maria Candelario (b) (4)	09 Apr 2021 00:44:54
	(b) (4)	

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Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (u) (4), (b) (6)	11 Apr 2021 08:40:45
User entered 'No (N)'	Maria Candelario (b) (4) (b) (4)	09 Apr 2021 00:44:54

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered '0'	(b) (4)	
	Maria Candelario (b) (4)	09 Apr 2021 00:44:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	09 Apr 2021 00:44:54

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	09 Apr 2021 00:44:54

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered empty.	(b) (4)	
	Maria Candelario (b) (4)	09 Apr 2021 00:44:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
	(b) (4)	
User entered empty.	Maria Candelario (b) (4)	09 Apr 2021 00:44:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
	(b) (4)	
User entered empty.	Maria Candelario (b) (4)	09 Apr 2021 00:44:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered empty.	(b) (4) Maria Candelario (b) (4)	09 Apr 2021 00:44:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	09 Apr 2021 00:44:54

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	09 Apr 2021 00:44:54

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered '1' reason for change: Data Entry Error	(b) (4) (u) (4), (b) (6)	11 Apr 2021 08:40:45
User entered '0'	Maria Candelario (b) (4) (b) (4)	09 Apr 2021 00:44:54

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
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	11 Apr 2021 08:37:19
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Apr 2021 08:37:19
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 00:44:54
User entered empty.	Maria Candelario (b) (4)	09 Apr 2021 00:44:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
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	11 Apr 2021 08:37:19
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Apr 2021 08:37:19
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 00:44:54
User entered empty.	Maria Candelario (b) (4)	09 Apr 2021 00:44:54
	(b) (4)	

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Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
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	11 Apr 2021 08:37:19
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Apr 2021 08:37:19
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 00:44:54
User entered empty.	Maria Candelario (b) (4)	09 Apr 2021 00:44:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

None

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered 'I'	(b) (4) Maria Candelario (b) (4) (b) (4)	09 Apr 2021 00:44:54

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	09 Apr 2021 00:44:54

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
	(b) (4)	
User entered '0'	Maria Candelario (b) (4)	09 Apr 2021 00:44:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	11 Apr 2021 08:40:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Apr 2021 08:40:45
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Apr 2021 08:40:45
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 00:44:54
User entered empty.	Maria Candelario (b) (4) (b) (4)	09 Apr 2021 00:44:54

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered empty.	(b) (4) Maria Candelario (b) (4) (b) (4)	09 Apr 2021 00:44:54

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered 'Subject presented to the site for OL visit Day 29, Urine pregnancy was done, the test result was positive. The subject was not dosed. The Event has been reported to the irb and will be reported to PPD.'	(b) (4)	
	Maria Candelario (b) (4)	09 Apr 2021 00:44:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Apr 2021 08:40:45
User entered '0'	System	09 Apr 2021 00:44:54

US3572076

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 08:17:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 00:44:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:17:25

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:55:38
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:16:36

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:25

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL; FERROUS FUMARATE; NORETHISTERONE ACETATE, PRODUCTSYNONYM: TAYTULLA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Sep 2020 08:15:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Sep 2020 08:15:53
Data point term sent to Coder	System	30 Aug 2020 15:40:34
User entered 'Taytulla (Ethinyl Estradiol / Norethindrone)'	Alisha Lutat (b) (4)	30 Aug 2020 15:39:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User closed query 'Per DM CLR: Indication = CONTRACEPTIVE, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	21 Jan 2021 08:31:57
Query 'Per DM CLR: Indication = CONTRACEPTIVE, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Jackie Ziegler (b) (4) (b) (4)	19 Jan 2021 19:55:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Jackie Ziegler (b) (4) (b) (4)	19 Jan 2021 19:55:43
User opened query 'Per DM CLR: Indication = CONTRACEPTIVE, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 08:54:04
User entered 'No (N)'	Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:39:52

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Contraceptive'	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 15:39:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '20/1'	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 15:39:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Other (OTHER)'	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 15:39:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User closed query 'Per DM CLR: Please remove extraneous details from the unit field such as numerical data (1) and (CAPSULE) and leave only the actual unit. Update as appropriate.' (Site from DM).	(b) (4) (u) (4), (b) (6)	28 Oct 2020 06:12:27
Query 'Per DM CLR: Please remove extraneous details from the unit field such as numerical data (1) and (CAPSULE) and leave only the actual unit. Update as appropriate.' answered with 'updated per query request ' (Site from DM).	Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 20:43:25
User entered 'MCG / MG' reason for change: Data Entry Error	Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 20:43:06
User opened query 'Per DM CLR: Please remove extraneous details from the unit field such as numerical data (1) and (CAPSULE) and leave only the actual unit. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 14:12:30
User entered 'mcg / 1mg (capsule)'	Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:39:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'once daily (QD)'	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 15:39:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:39:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Oral (ORAL)'	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 15:39:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:39:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'UN Jan 2020'	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 15:39:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:25

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:39:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 15:39:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	30 Aug 2020 15:39:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4)	30 Aug 2020 15:39:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	30 Aug 2020 15:39:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	30 Aug 2020 15:39:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:17:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Aug 2020 15:39:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:25

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:53
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 20:15:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 20:15:37
Data point term sent to Coder	System	31 Aug 2020 20:14:31
User entered 'Ibuprofen'	Jasmine Ali (b) (4)	31 Aug 2020 20:13:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:25

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:53
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:13:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:25

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:53
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'headache'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:13:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:25

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:53
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '200'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:13:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:25

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:53
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'mg (mg)'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:13:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:25

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:53
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:13:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:25

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:53
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'as needed (PRN)'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:13:35
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:25

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:53
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) Jasmine Ali (b) (4) (b) (4)	31 Aug 2020 20:13:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:25

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:53
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Oral (ORAL)'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:13:35

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:25

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:53
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) Jasmine Ali (b) (4) (b) (4)	31 Aug 2020 20:13:35

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:53
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '25 Aug 2020'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:13:35

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:25

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:53
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '0'	(b) (4) Jasmine Ali (b) (4)	31 Aug 2020 20:13:35

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:25

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:53
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
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) (u) (4), (b) (6)	09 Nov 2020 08:32:05
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 'stop date updated ' (Site from DM).	Alisha Lutat (b) (4) (b) (4)	05 Nov 2020 18:14:46
User entered 'No (N)' reason for change: Data Entry Error	Alisha Lutat (b) (4) (b) (4)	05 Nov 2020 18:14:18
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)	02 Nov 2020 12:02:44
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	31 Aug 2020 20:13:35

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:53
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '25 Aug 2020' reason for change: Data Entry Error	(b) (4)	05 Nov 2020 18:14:18
User entered empty.	Alisha Lutat (b) (4)	31 Aug 2020 20:13:35
	(b) (4)	

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:25

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:53
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of HEADACHE in eDiary. Please note that this CM was given at Day 8 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 06:28:43
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of HEADACHE in eDiary. Please note that this CM was given at Day 8 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' answered with 'ae is noted as beginning on 8/24/20- medication taken next day' (Site from DM).	Jackie Ziegler (b) (4) (b) (4)	19 Jan 2021 19:57:22
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of HEADACHE in eDiary. Please note that this CM was given at Day 8 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 08:55:14
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	31 Aug 2020 20:13:35

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:53
User entered empty.	System	31 Aug 2020 20:13:35

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:53
User entered empty.	System	31 Aug 2020 20:13:35

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:17:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:53
User entered empty.	System	31 Aug 2020 20:13:35

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:25

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: ANTI ALLERGIC AGENTS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 12:03:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 12:03:39
Data point term sent to Coder	System	09 Sep 2020 15:48:42
User entered 'Allergy medication-unknown name'	Jasmine Ali (b) (4)	09 Sep 2020 15:48:14

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'No (N)'	(b) (4) Jasmine Ali (b) (4) (b) (4)	09 Sep 2020 15:48:14

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Allergies'	(b) (4) Jasmine Ali (b) (4) (b) (4)	09 Sep 2020 15:48:14

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'unknown'	(b) (4) Jasmine Ali (b) (4) (b) (4)	09 Sep 2020 15:48:14

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Other (OTHER)'	(b) (4) Jasmine Ali (b) (4) (b) (4)	09 Sep 2020 15:48:14

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'unknown'	(b) (4) Jasmine Ali (b) (4) (b) (4)	09 Sep 2020 15:48:14

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'as needed (PRN)'	(b) (4) Jasmine Ali (b) (4) (b) (4)	09 Sep 2020 15:48:14

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:25

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) Jasmine Ali (b) (4) (b) (4)	09 Sep 2020 15:48:14

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'Oral (ORAL)'	(b) (4) Jasmine Ali (b) (4) (b) (4)	09 Sep 2020 15:48:14

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) Jasmine Ali (b) (4) (b) (4)	09 Sep 2020 15:48:14

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '3 Sep 2020'	(b) (4) Jasmine Ali (b) (4) (b) (4)	09 Sep 2020 15:48:14

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered '0'	(b) (4) Jasmine Ali (b) (4) (b) (4)	09 Sep 2020 15:48:14

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
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) (v) (4), (b) (6)	09 Nov 2020 08:27:49
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 'end date updated ' (Site from DM).	Alisha Lutat (b) (4) (b) (4)	05 Nov 2020 18:17:14
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)	02 Nov 2020 12:03:23
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	09 Sep 2020 15:48:14

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:25

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered empty.	(b) (4) Jasmine Ali (b) (4) (b) (4)	09 Sep 2020 15:48:14

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:25

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the ALLERGIES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of ALLERGIES did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (u) (4), (b) (6)	28 Oct 2020 06:09:57
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the ALLERGIES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of ALLERGIES did not meet the AE reporting criteria.' answered with 'pt contacted; confirmed she has seasonal allergies; Med hx updated.' (Site from DM).	Alisha Lutat (b) (4) (b) (4)	22 Oct 2020 21:15:50
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the ALLERGIES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of ALLERGIES did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 17:22:07

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jasmine Ali (b) (4) (b) (4)	09 Sep 2020 15:48:14

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:25

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 15:48:14

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:25

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 15:48:14

US3572076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:17:25

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 15:48:14

US3572076

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:17:25

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:23:30
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	12 Mar 2021 16:03:06

US3572076

Folder: SAE USA-US091-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 19:29:06
User entered 'USA-US091-2021-MRNA-1273-P301000016'	System	12 Apr 2021 19:28:25

US3572076

Folder: SAE USA-US091-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 19:29:06
User entered 'Yes (Y)'	System	12 Apr 2021 19:28:25

US3572076

Folder: SAE USA-US091-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 19:29:06
User entered 'No (N)'	System	12 Apr 2021 19:28:25

US3572076

Folder: SAE USA-US091-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 19:29:06
User entered 'No (N)'	System	12 Apr 2021 19:28:25

US3572076

Folder: SAE USA-US091-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 19:29:06
User entered 'No (N)'	System	12 Apr 2021 19:28:25

US3572076

Folder: SAE USA-US091-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 19:29:06
User entered 'No (N)'	System	12 Apr 2021 19:28:25

US3572076

Folder: SAE USA-US091-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 19:29:06
User entered 'No (N)'	System	12 Apr 2021 19:28:25

US3572076

Folder: SAE USA-US091-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 19:29:06
User entered 'Yes (Y)'	System	12 Apr 2021 19:28:25

US3572076

Folder: SAE USA-US091-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 19:29:06
User entered 'Milton'	System	12 Apr 2021 19:28:25

US3572076

Folder: SAE USA-US091-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 19:29:06
User entered 'Haber'	System	12 Apr 2021 19:28:25

US3572076

Folder: SAE USA-US091-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:25

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 19:29:06
User entered '2344 Laguna Del Mar, Suite 201'	System	12 Apr 2021 19:28:25

US3572076

Folder: SAE USA-US091-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:25

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 19:29:06
User entered 'Laredo'	System	12 Apr 2021 19:28:25

US3572076

Folder: SAE USA-US091-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:25

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 19:29:06
User entered 'TX'	System	12 Apr 2021 19:28:25

US3572076

Folder: SAE USA-US091-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 19:29:06
User entered '78041'	System	12 Apr 2021 19:28:25

US3572076

Folder: SAE USA-US091-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered 'US'	(b) (4) System	12 Apr 2021 19:29:13

US3572076

Folder: SAE USA-US091-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 19:29:13

US3572076

Folder: SAE USA-US091-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:25

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 19:29:06
User entered 'USA-US091-2021-MRNA-1273-P301000016'	System	12 Apr 2021 19:28:25

US3572076

Folder: SAE USA-US091-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:25

Serious

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 19:29:06
User entered 'Yes (Y)'	System	12 Apr 2021 19:28:25

US3572076

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 19:29:06
User entered 'No (N)'	System	12 Apr 2021 19:28:25

US3572076

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 19:29:06
User entered 'No (N)'	System	12 Apr 2021 19:28:25

US3572076

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 19:29:06
User entered 'No (N)'	System	12 Apr 2021 19:28:25

US3572076

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 19:29:06
User entered 'No (N)'	System	12 Apr 2021 19:28:25

US3572076

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 19:29:06
User entered 'No (N)'	System	12 Apr 2021 19:28:25

US3572076

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 19:29:06
User entered 'Yes (Y)'	System	12 Apr 2021 19:28:25

US3572076

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 19:29:06
User entered 'Milton'	System	12 Apr 2021 19:28:25

US3572076

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 19:29:06
User entered 'Haber'	System	12 Apr 2021 19:28:25

US3572076

Folder: SAE USA-US091-2021-MRNA-1273-P301000016

Form: Safety Report Form

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[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 19:29:06
User entered '2344 Laguna Del Mar, Suite 201'	System	12 Apr 2021 19:28:25

US3572076

Folder: SAE USA-US091-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:25

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 19:29:06
User entered 'Laredo'	System	12 Apr 2021 19:28:25

US3572076

Folder: SAE USA-US091-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:25

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 19:29:06
User entered 'TX'	System	12 Apr 2021 19:28:25

US3572076

Folder: SAE USA-US091-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Apr 2021 19:29:06
User entered '78041'	System	12 Apr 2021 19:28:25

US3572076

Folder: SAE USA-US091-2021-MRNA-1273-P301000016

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered 'US'	(b) (4) System	12 Apr 2021 19:29:13

US3572076

Folder: SAE USA-US091-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 10 Jun 2021 08:17:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 19:29:13

US3572076

Folder: SAE USA-US091-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:17:25

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered '12/Apr/2021 15:29'	(b) (4) System	12 Apr 2021 19:29:13

US3572076

Folder: SAE USA-US091-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:17:25

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:31:38
User entered 'I'	(b) (4) (u) (4), (b) (6)	12 Apr 2021 19:29:13